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☐ *Individual appearing without attorney*
☒ *Attorney for:* Amy L. Goldman, Chapter 7 Trustee

FOR COURT USE ONLY

UNITED STATES BANKRUPTCY COURT
CENTRAL DISTRICT OF CALIFORNIA - SAN FERNANDO VALLEY DIVISION

In re:
SALUBRIOUS PHARMACEUTICAL, LLC

Debtor(s).

CASE NO.: 1:15-bk-11118-MT

CHAPTER: 7

NOTICE OF SALE OF ESTATE PROPERTY

Sale Date: August 3, 2016 **Time:** 11:00 a.m.

Location: United States Bankruptcy Court, Courtroom 302, 21041 Burbank Blvd., Woodland Hills, CA 91367

Type of Sale: ☐ Public ☒ Private **Last date to file objections**: July 20, 2016

Description of property to be sold: The estate's interest in certain pharmaceutical patents pending approval by the United States Patent Office and the European Patent Organization (the "EPO") and related intellectual property, as well as Debtor's interest in any and all assets related thereto. See attached Motion for Order (1) Approving Sale of Certain of the Debtor's Assets Under Asset Purchase Agreement; (2) Approving Overbid Procedure; (3) Determining That Buyer is Entitled to §363(M) Protection; Memorandum of Points and Authorities; Declarations in Support Thereof

Terms and conditions of sale: The proposed sale will be on an "as is" and "where is" basis, and without any representations and/or warranties except as set forth herein in the APA, subject to Bankruptcy Court approval and overbid. The Trustee also seeks authority from this Court to solicit and consider overbids concerning the sale of the Assets at the hearing on the Motion. Finally, the Trustee requests that the Court find that the Buyer is a good faith purchaser, entitled to the protections afforded under section 363(m) of the Bankruptcy Code.

Proposed sale price: Fifty Thousand and One Dollar ($50,001.00). See the Motion for full details.

Overbid procedure (*if any*): See the Motion for full details.

If property is to be sold free and clear of liens or other interests, list date, time and location of hearing:

August 3, 2016
11:00 a.m.
United States Bankruptcy Court
Courtroom 302
21041 Burbank Blvd.
Woodland Hills, CA 91367

Contact person for potential bidders (*include name, address, telephone, fax and/or email address*):

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LEWIS BRISBOIS BISGAARD & SMITH LLP
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Los Angeles, CA 90071
Telephone: 213.250.1800 / Facsimile: 213.250.7099
doah.kim@lewisbrisboiscom

Date: June 29, 2016

Proposed Sale Price

The Assets are being sold as is, where is, without any guaranty or warranty. The Trustee makes no opinion on the tax consequences of the proposed sale.

Sales price $50,001.00

Overbid Procedure

1. Each party participating in the overbid process must notify the Trustee not less than three days prior to the hearing on the Motion and prior to the hearing on the Motion a deposit in the form of a cashier's check or money order made payable to the Trustee in the amount of $55,001.00. The $55,001.00 deposit shall not be refundable if such party is the successful bidder and is thereafter unable to complete the purchase of the Assets according to the terms set forth herein. The initial over bid must be $5,000.00 more than that of the proposed Buyer;

2. In the event there is a successful bidder who is not the Buyer, there is no subordination of the Claims. As such, any overbid must not only exceed the cash Purchase Price of $50,001.00, by $5,000.00, but allow for a substantial distribution to, at the least, of all timely-filed allowed unsecured claims without subordination of the Claims, or has obtained an agreement for the subordination of Claimants' claims. All other terms must be the same as proposed by the Buyer;

3. Any party participating in the overbid process shall not be precluded from continuing to make bids after initially passing his/her/its turn or turns to overbid; and

4. The successful bidder (including the Buyer) must pay the full amount of the successful bid to the Trustee and close the sale transaction within two (2) calendar days after the entry of a final, non-appealable order granting the Motion. In the event that the Buyer is not the successful bidder of the Assets, the successful bidder shall then become the Buyer under the same terms and conditions as set forth herein and shall waive all contingencies regarding the purchase of the Assets. Furthermore, if the successful bidder cannot deliver the balance of the Purchase Price within the above-referenced period, the Trustee shall be authorized to accept the offer made by the next highest bidder, if any, and the successful bidder's deposit shall be non-refundable.

SEE ATTACHED MOTION

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Attorneys for AMY L. GOLDMAN,
Chapter 7 Trustee

UNITED STATES BANKRUPTCY COURT

CENTRAL DISTRICT OF CALIFORNIA

SAN FERNANDO DIVISION

In re	Case No.: 1:15-bk-11118-MT
SALUBRIOUS PHARMACEUTICAL LLC,	Chapter 7
Debtors.	**TRUSTEE'S MOTION FOR ORDER (1) APPROVING SALE OF CERTAIN OF THE DEBTOR'S ASSETS UNDER ASSET PURCHASE AGREEMENT; (2) APPROVING OVERBID PROCEDURE; (3) DETERMINING THAT BUYER IS ENTITLED TO §363(m) PROTECTION; MEMORANDUM OF POINTS AND AUTHORITIES; DECLARATIONS IN SUPPORT THEREOF**
	[LOCAL BANKRUPTCY RULES 9013-1(f) and 9013-1(o)(1); 11 U.S.C. §363(b)]
	Hearing Date: Date: August 3, 2016 Time: 11:00 a.m. Ctrm: 302 21041 Burbank Boulevard Woodland Hills, CA 91367

TO THE HONORABLE MAUREEN A. TIGHE, UNITED STATES BANKRUPTCY

JUDGE:

Pursuant to sections 363(b) and (m) of Title 11 of the United States Code (the "Bankruptcy Code"), Amy L. Goldman, Chapter 7 Trustee ("Trustee" or "Movant") for the bankruptcy estate of Salubrious Pharmaceutical, LLC (the "Debtor"), hereby files this motion (the "Motion") for authority to sell certain of the Debtor's assets further described herein (collectively, the "Assets") to Honor C.W. M.D., LLC, a California limited liability company (the "Buyer"). The sale terms and conditions of the are memorialized in the Asset Purchase Agreement dated June ___, 2016 (the "APA") attached as **Exhibit "A"** to the Trustee's Declaration ("Goldman Declaration") annexed hereto. In support of the Motion, the Trustee respectfully represents as follows:

MEMORANDUM OF POINTS AND AUTHORITIES

I.

INTRODUCTION

The Trustee, through this Motion, seeks authority to sell the estate's interest in certain pharmaceutical patents pending approval by the United States Patent Office and the European Patent Organization (the "EPO") and related intellectual property, as well as Debtor's interest in any and all assets related thereto (collectively, "Assets"). The patents are for an antigen based antibody complex for the purpose of ameliorating neurological diseases. Trustee is informed the United States Patent Office requires a double blind study. The Assets will be sold by to Buyer for the purchase price of fifty thousand and one dollars ($50,001.00) (the "Purchase Price"), which has fully been tendered by Buyer to the Trustee in the form of three separate checks.

The proposed sale will be on an "as is" and "where is" basis, and without any representations and/or warranties except as set forth herein in the APA, subject to Bankruptcy Court approval and overbid. The Trustee also seeks authority from this Court to solicit and consider overbids concerning the sale of the Assets at the hearing on the Motion. Finally, the Trustee requests that the Court find that the Buyer is a good faith purchaser, entitled to the protections afforded under section 363(m) of the Bankruptcy Code.

The Trustee believes that the proposed sale is in the best interest of the bankruptcy estate and should be approved as: (1) consideration for the sale is reasonable and (2) the bankruptcy estate will

benefit as a result of the sale.

II.

STATEMENT OF FACTS

1. The instant bankruptcy case (the "Bankruptcy Case") was commenced by the filing of a voluntary petition for relief under chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code") on April 1, 2015 (the "Filing Date").

2. On July 20, 2015, creditor Pharmo LLC ("Pharmo") filed a motion to convert case from chapter 11 to one under chapter 7 (Dkt. No. 36), which this Court granted pursuant to the order entered on September 3, 2015 (Dkt. No. 46).

3. Amy L. Goldman was appointed the Chapter 7 Trustee of this Bankruptcy Case on September 10, 2015 (Dkt. No. 49).

4. On September 16, 2015, Debtor filed a notice of appeal and statement of election to U.S. District Court of the order converting the Bankruptcy Case to chapter 7 (Dkt. No. 51). To date, the Debtor has not requested for a stay pending appeal nor posted a bond.

5. Among the potential assets of this bankruptcy estate currently known to the Trustee include, without limitation, interests in certain pharmaceutical patents pending in the United States and EPO and other related intellectual property (the "Assets"). Upon conducting a preliminary analysis of the Assets, the Trustee has determined that they may have sufficient equity to benefit the estate's creditors if administered by the Trustee.

6. Debtor's Schedule B lists the assets as "Patents Pending" with a value of $100,000,000.00. Debtor claims United States patents are pending as #12/426,838 and #12/759.620.

7. The United States Patent Office shows Debtor filed Application Nos. 20100330117 and 20100080826 and the EPO shows application Nos. EP11769524 and EP08816736.

8. Based on the foregoing and subject to Bankruptcy Court approval, the Trustee now seeks to sell the Assets to the Buyer pursuant to the terms and conditions set forth in the APA and incorporated herein by reference to recover money for creditors.

9. Pursuant to the Agreement, the Trustee has agreed to sell the Assets to Buyer for the

purchase price of $50,001.00, which the Trustee has received.

10. The claims bar dates to file governmental and non-governmental claims in this Bankruptcy Case was September 28, 2015 and March 28, 2016, respectively.

11. To date, there are a total of eight claims filed in this Bankruptcy Case, totaling approximately $12,629,000.00.

12. On April 14, 2015, Maricela S. Wilde ("Wilde") filed proof of claim number 1 as a general unsecured claim in the amount of $4,668,567.30 ("Claim 1").

13. On August 11, 2015, Robert W. and Priscilla Boatman (together, "Boatman") filed proof of claim number 2 as a general unsecured claim in the amount of $200,000.00 ("Claim 2").

14. On August 14, 2015, Pharmo filed proof of claim number 3 as a general unsecured claim in the amount of $2,230,000.00 ("Claim 3").

15. On August 14, 2015, John E. Sweeney ("Sweeney") filed proof of claim number 4 as a general unsecured claim in the amount of $5,000,000.00 ("Claim 4").

16. On August 13, 2015, Norman Perbil ("Perbil") filed proof of claim number 5 as a general unsecured claim in the amount of $115,000.00 ("Claim 5").

17. On August 18, 2015, Robert C. Baker ("Baker") filed proof of claim number 6 as a general unsecured claim in the amount of $407,000.00 ("Claim 6").

18. As part of the proposed sale, Wilde, Boatman, Pharmo, Sweeney, and Baker (collectively, the "Claimants"), as principals of the buyer, have agreed to subordinate their respective claims to those of the allowed general unsecured claims in the Bankruptcy Case and to Claim 5 of Perbil, pursuant to separate subordination of claim agreements entered by and between the Trustee and the Claimants. Norman Perbil, an other principal of the buyer has indicated that he will reduce his claim to $15,000.00.

19. The Trustee makes no opinion on the tax consequences of the proposed sale.

20. The Trustee will receive a minimum of cash as follows:

Sales price	$50,001.00

21. As part of the sale, the Claimants have agreed to subordinate its claim to those of all

timely filed allowed claims and Claim 5 filed by Normal Perbil.

22. The Trustee has determined that the secured claims against the estate and the assets being sold appear to be as follows:

Franchise Tax Board ("FTB")	$8,434.41.00

23. To the extent the claim of the FTB is secured by the Assets, the FTB lien will attach to the proceeds of the sale.

III.

ARGUMENT

A. The Court Should Authorize The Trustee To Sell The Assets To Buyer Under The Terms Of The Asset Purchase Agreement

Section 363(b) of the Bankruptcy Code provides, in pertinent part, that the trustee, "after notice and a hearing, may use, sell, or lease, other than in the ordinary course of business, property of the estate… ." 11 U.S.C. § 363(b)(1). In determining whether any sale of assets out of the ordinary course of business should be approved, the court must find some rational, articulated business purpose. See, e.g., Stephens Indus., Inc. v. McClung, 789 F.2d 386, 390 (6th Cir. 1986); In re Continental Air Lines, Inc., 780 F.2d 1223, 1226 (5th Cir. 1986); In re Lionel Corp., 722 F.2d 1063, 1070 (2d Cir. 1983). The Ninth Circuit Bankruptcy Appellate Panel in Walter v. Sunwest Bank (In re Walter), 83 B.R. 14, 19 (9th Cir. BAP 1988) adopted the reasoning of the Fifth Circuit in In re Continental Airlines, supra, and In re Lionel Corp., supra, and articulated the following applicable standard under section 363(b):

> Whether the proferred business justification is sufficient depends on the case. As the Second Circuit held in Lionel, the bankruptcy judge should consider all salient factors pertaining to the proceeding and, accordingly, act to further the diverse interests of the Debtor, creditors and equity holders, alike.

Id. In addition to determining whether a sufficient business reason exists for the sale, a bankruptcy court should also consider whether the proposed sale is in the best interest of the estate, which in turn warrants consideration of the following factors: (1) that terms of the sale are fair and reasonable; (2) that the proposed sale has been adequately marketed; (3) that the proposed sale terms have been properly negotiated and proposed in good faith; and (4) that the purchaser is involved in

an "arms-length" transaction with the seller. See generally, In re Wilde Horse Enterprises, Inc., 136 Bankr. 830 (Bankr. C.D. Cal. 1991) ("in approving any sale outside the ordinary course of business, the court must not only articulate a sufficient business reason for the sale, it must further find it is in the best interest of the estate, i.e., it is fair and reasonable, that it has been given adequate marketing, that it has been negotiated and proposed in good faith, and that it is an 'arms-length' transaction"); Matter of Phoenix Steel Corp., 82 Bankr. 334, 335-356 (Bankr. D. Del. 1987) (In determining whether a proposed sale of equipment was proper under Section 363, court considered whether the terms of proposed sale were fair and equitable, whether there was a good business reason for completing the sale and whether the transaction was proposed in good faith); In re Alves, 52 Bankr. 353 (Bankr. D.R.I. 1985) (factors concerning whether sale of property under Section 363 should be approved concerned integrity of sale and preservation of the best interest of bankruptcy estate).

The Trustee submits that the facts pertaining to the proposed sale of the Assets to the Buyer in accordance with the terms and conditions of the APA satisfies all of the applicable elements discussed above, demonstrates the Trustee's sound business judgment, serves the best interests of the estate and its creditors and thus, warrants the approval of the Bankruptcy Court.

The facts surrounding this proposed sale are unusual, however, considering the totality of the circumstances, the Trustee firmly believes, in her business judgment, that the sale of the Assets to Buyer is fair, reasonable and in the best interests of this estate as further explained below. Also, an immediate sale will not only allow for the estate to eliminate assets on an "as is," "where is" bases to recover money for creditors, but would help maximize the value of the Assets sold.

It cannot be disputed that the Claimants' claims constitute the majority of the total claims in this Estate. However, to effectuate this sale, the Claimants have offered and agreed to subordinate their respective claims (i.e., Claim 1, Claim 2, Claim 3, Claim 4, and Claim 6, collectively, the "Claims") in the allowed amount of approximately $12,505,567.00, to all claims other timely-filed allowed claims as well as Claim 5 of Normal Perbil in the amount of $115,000.00. The subordination of the Claims is a significant aspect of the proposed sale in that it would allow other general unsecured claims to paid a substantial dividend, thereby receiving a greater distribution (or a distribution at all) than what they would receive absent the subordination.

Trustee believes that Claim No. 5, of Perbil, could be reduced from $115,000.00 to $15,000.00. Trustee has received an email from Sweeney which appears to state that Perbil will agree to such reductions. This means that the proposed sale may generate close to a 100% distribution in this case.

Lastly, at all relevant times herein, the Buyer and the Trustee have dealt in good faith and have engaged in an "arms-length" transaction in an effort to sell the Assets the Buyer subject to Bankruptcy Court approval.

The proposed sale to Buyer would most likely allow payment of all of the anticipated administrative expenses and secured claims in this Bankruptcy Case, but would also allow as the claims are known, to date, a substantial distribution of all timely-filed or scheduled general unsecured claims due to the Claimants' subordination of their collective $12.5 million claims. Accordingly, for all of the reasons stated above, the proposed sale of the Assets to Buyer should be approved.

B. The Court Should Find That The Buyer Is A Good Faith Purchaser Within The Meaning Of 11 U.S.C. § 363(m)

Section 363(m) of the Bankruptcy Code authorizes the Court to make a finding that a buyer is a good faith purchaser. A purchaser of property is protected from the effects of reversal on appeal of the authorization to sell or lease as long as the Court finds that the purchaser acted in good faith and the appellant fails to obtain a stay of the sale. See 11 U.S.C. § 363(m) (2004). Although the Bankruptcy Code does not define "good faith," courts have provided guidance as to the appropriate factors to consider. See In re Pine Coast Enterprise, Ltd., 147 B.R. 30, 33 (Bankr. N.D. Ill. 1992) ("The requirement that a purchaser act in good faith speaks to the integrity of its conduct in the course of the sale proceeding"); Kham and Nate's Shoes No. 2 v. First Bank, 908 F.2d 1351, 1355 (7th Cir. 1990) ("The purpose of § 363(m) is to disable courts from backtracking on promises with respect to bankruptcy sales in the absence of bad faith"). In In re M Capital Corp., 290 B.R. 743 (9th Cir. 2003), the BAP held that a bankruptcy court may not make a finding of good faith in the absence of evidence, but may make such a finding if appropriate evidence is presented.

In the instant case, the Trustee requests that the Court make a finding that the Buyer is a one

good faith purchaser within the meaning of section 363(m). As set forth in the Declaration of John Sweeney, (a) the Buyer has no connection to the Trustee, the Estate or the creditors, save that the principals of the Buyer are creditors of the bankruptcy estate. In addition, Sweeney has represented debtor in various matters as its attorney (b) the terms of the sale were negotiated at arms-length over an extended period of time, and (c) the proposed Purchase Price is fair consideration. Trustee has been informed that Sweeney has represented Debtor and its principal, George Nelson ("Nelson"), in various matters, as their attorney. The Claimants claim to have invested funds with Debtor and/or Nelson for the exploration of the patents being sold.

In a declaration filed October 9, 2015, as docket 63-3, Nelson admits that two of the Claimants, Pharmo and Sweeney, together with Perbil, have contributed $110,000.00 total, and that a total of $3,000,000.00 was contributed from all sources.

The relationship between Nelson and the claimants has become acrimonious, and Nelson has accused the prior attorney for Nelson and Debtor, Sweeney, of conflicts of interests and other acts.

Trustee has repeatedly requested documents from Debtor but Nelson has not yet provided any documents whatsoever. He has also not yet appeared for the 341(a) meeting, claiming medical issues.

Trustee has been informed that unless somebody takes over the patents the applications will expire and the patents will become valueless.

Trustee and her counsel have been negotiating with Sweeney for the sale and purchase of the IP since October, 2015. On October 9, 2015, Trustee's counsel also inquired of Debtor's counsel whether Debtor's principal, Nelson, was interested in purchasing the IP. No response was received.

As such, a finding of good faith within the meaning of section 363(m) is appropriate.

C. The Proposed Overbid Procedure Will Not Prejudice Any Interested Party And May Substantially Benefit The Estate

While the Trustee is prepared to accept the offer for the estate's interest in the Assets as set forth above, she is also interested in obtaining the maximum price for the same. Given the unique structure of the proposed sale, the Trustee requests that the Court authorize her to implement an overbid procedure regarding the sale of the Assets in the manner set forth below.

In order for any party to participate in an overbid procedure regarding the acquisition of the estate's interest in the Assets, the Trustee requests that the parties comply with the following provisions:

1. Each party (including the Buyer) must be present either physically or telephonically at the hearing on the Motion or represented by an individual or individuals with the authority to participate in the overbid process;

2. Each party participating in the overbid process must notify the Trustee not less than three days prior to the hearing on the Motion and prior to the hearing on the Motion a deposit in the form of a cashier's check or money order made payable to the Trustee in the amount of $55,001.00. The $55,001.00 deposit shall not be refundable if such party is the successful bidder and is thereafter unable to complete the purchase of the Assets according to the terms set forth herein. The initial over bid must be $5,000.00 more than that of the proposed Buyer;

3. In the event there is a successful bidder who is not the Buyer, there is no subordination of the Claims. As such, any overbid must not only exceed the cash Purchase Price of $50,001.00, by $5,000.00, but allow for a substantial distribution to, at the least, of all timely-filed allowed unsecured claims without subordination of the Claims, or has obtained an agreement for the subordination of Claimants' claims;[1] All other terms must be the same as proposed by the Buyer;

4. Any party participating in the overbid process shall not be precluded from continuing to make bids after initially passing his/her/its turn or turns to overbid; and

5. The successful bidder (including the Buyer) must pay the full amount of the successful bid to the Trustee and close the sale transaction within two (2) calendar days after the entry of a final, non-appealable order granting the Motion. In the event that the Buyer is not the successful bidder of the Assets, the successful bidder shall then become the Buyer under the same terms and conditions as set forth herein and shall waive all contingencies regarding the purchase of the Assets. Furthermore, if the successful bidder cannot deliver the balance of the Purchase Price

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[1] The Trustee believes the value of the subordination to be approximately $12,505,567.30.

within the above-referenced period, the Trustee shall be authorized to accept the offer made by the next highest bidder, if any, and the successful bidder's deposit shall be non-refundable.

IV.

WAIVER OF STAY UNDER RULE 6004(h)

It is requested that the Court waive the stay under Federal Rules of Bankruptcy Procedure 6004(h) and that an order approving the sale is effective immediately.

V.

CONCLUSION

Based on the foregoing, the Trustee respectfully requests that the Court enter an Order: (1) granting the within Motion; (2) authorizing the sale of the estate's interest in the Assets to the Buyer pursuant to 11 U.S.C. §363(b) in accordance with the terms of the APA; (3) approving the terms and conditions of the sale of the estate's interest in the Assets set forth in this Motion and APA; (4) authorizing the Trustee to execute thed APA and all related documents and/or take further action to consummate the sale of the Assets; (5) finding that the Buyer is a good faith purchaser within the meaning of 11 U.S.C. §363(m); (6) approving the form and manner of notice provided by the Trustee, waiving the stay under Rule 6004(h); and (7) granting all other appropriate relief.

DATED: June 29, 2016

LEWIS BRISBOIS BISGAARD & SMITH LLP

By: _____

ANNIE VERDRIES
DOAH KIM
Attorneys for AMY L. GOLDMAN,
Chapter 7 Trustee

DECLARATION OF AMY L. GOLDMAN

I, AMY L. GOLDMAN, hereby declare as follows:

1. I am the duly appointed, qualified and acting Chapter 7 Trustee for the bankruptcy estate of Salubrious Pharmaceutical LLC ("Debtor").

2. This declaration is made in support of the motion ("Motion") for authority to sell certain of the Debtor's assets pursuant to the Asset Purchase Agreement (the "APA") attached hereto as **Exhibit "A."**

3. Except as otherwise stated herein, I have personal knowledge of the matters discussed below, and if called as a witness I could and would competently testify thereto.

4. The records reflect that the instant bankruptcy case (the "Bankruptcy Case") was commenced by the filing of a voluntary petition for relief under chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code") on April 1, 2015 (the "Filing Date").

5. The records reflect that on July 20, 2015, creditor Pharmo LLC ("Pharmo") filed a motion to convert case from chapter 11 to one under chapter 7 (Dkt. No. 36), which this Court granted pursuant to the order entered on September 3, 2015 (Dkt. No. 46).

6. I was appointed the Chapter 7 Trustee of this Bankruptcy Case on September 10, 2015 (Dkt. No. 49).

7. On September 16, 2015, Debtor filed a notice of appeal and statement of election to U.S. District Court of the order converting the Bankruptcy Case to chapter 7 (Dkt. No. 51). To date, the Debtor has not requested for a stay pending appeal nor posted a bond.

8. Among the potential assets of this bankruptcy estate currently known to the Trustee include, without limitation, interests in certain pharmaceutical patents pending in the United States Patent Office and the European Patent Office ("EPO") and other related intellectual property (the "Assets"). Upon conducting a preliminary analysis of the Assets, I have determined that they may have sufficient equity to benefit the estate's creditors if administered.

9. Debtor's Schedule B lists the assets as "Patents Pending" with a value of $100,000,000.00. Debtor claims United States patents are pending as #12/426,838 and #12/759.620.

10. Based on the foregoing and subject to Bankruptcy Court approval, I now seek to sell the Assets to the Buyer pursuant to the terms and conditions set forth in the APA and incorporated herein by reference to recover money for creditors.

11. I have agreed to sell the Assets to Honor C.W. M.D., LLC ("Buyer") for the purchase price of $50,001.00, which I have received.

12. The claims bar dates to file governmental and non-governmental claims in this Bankruptcy Case was September 28, 2015 and March 28, 2016, respectively.

13. Based on my review of the claims register, there are a total of eight claims filed in this Bankruptcy Case, totaling approximately $12,629,000.00.

14. On April 14, 2015, Maricela S. Wilde ("Wilde") filed proof of claim number 1 as a general unsecured claim in the amount of $4,668,567.30 ("Claim 1").

15. On August 11, 2015, Robert W. and Priscilla Boatman (together, "Boatman") filed proof of claim number 2 as a general unsecured claim in the amount of $200,000.00 ("Claim 2").

16. On August 14, 2015, Pharmo filed proof of claim number 3 as a general unsecured claim in the amount of $2,230,000.00 ("Claim 3").

17. On August 14, 2015, John E. Sweeney ("Sweeney") filed proof of claim number 4 as a general unsecured claim in the amount of $5,000,000.00 ("Claim 4").

18. On August 13, 2015, Norman Perbil ("Perbil") filed proof of claim number 5 as a general unsecured claim in the amount of $115,000.00 ("Claim 5").

19. On August 18, 2015, Robert C. Baker ("Baker") filed proof of claim number 6 as a general unsecured claim in the amount of $407,000.00 ("Claim 6").

20. As part of the proposed sale, Wilde, Boatman, Pharmo, Sweeney, and Baker (collectively, the "Claimants"), as principals of the buyer, have agreed to subordinate their respective claims to those of the allowed general unsecured claims in the Bankruptcy Case and to Claim 5 of Perbil, pursuant to separate subordination of claim agreements entered by and between the Trustee and the Claimants. Norman Perbil, an other principal of the buyer has indicated that he will reduce his claim to $15,000.00.

21. The Trustee makes no opinion on the tax consequences of the proposed sale.

22. The Trustee will receive a minimum of cash as follows:

Sales price	$50,001.00

23. As part of the sale, the Claimants have agreed to subordinate its claim to those of all timely filed allowed claims and Claim 5 filed by Normal Perbil.

24. I have determined that the secured claims against the estate and the assets being sold appear to be as follows:

Franchise Tax Board ("FTB")	$8,434.41.00

25. To the extent the claim of the FTB is secured by the Assets, the FTB lien will attach to the proceeds of the sale.

26. At all relevant times herein, the Buyer and I, with the assistance of my counsel, have dealt in good faith and have engaged in an "arms-length" transaction in an effort to sell the Assets the Buyer subject to Bankruptcy Court approval. The negotiations commenced in October 2015.

27. The proposed sale to Buyer would most likely allow payment of all of the anticipated administrative expenses and secured claims in this Bankruptcy Case, but would also allow as the claims are known, to date, a substantial distribution of all timely-filed or scheduled general unsecured claims due to the Claimants' subordination of their collective $12.5 million claims.

28. I request that the Court make a finding that the Buyer is a good faith purchaser within the meaning of section 363(m). As set forth in the Declaration of John Sweeney ("Sweeney"), (a) the Buyer has no connection to the Trustee, the Estate or the creditors, save that the principals of the Buyer are creditors of the bankruptcy estate. I have been informed that Sweeney has represented Debtor and its principal, George Nelson ("Nelson"), in various matters, as their attorney. The Claimants claim to have invested funds with Debtor and/or Nelson for the exploration of the patents being sold.

As part of the negotiations for the sale of the assets I did not make any concessions or provide any benefits to Buyer for their principals' status as creditors and possibly equity claimants. In fact, I insisted that five claims were subordinated and one reduced to facilitate the sale.

29. In a declaration filed October 9, 2015, as docket 63-3, Nelson admits that two of the

Claimants, Pharmo and Sweeney, together with Perbil, have contributed $110,000.00 total, and that a total of $3,000,000.00 was contributed from all sources.

30. I understand that the relationship between Nelson and the claimants has become acrimonious, and Nelson has accused the prior attorney for Nelson and Debtor, Sweeney, of conflicts of interests and other acts.

31. I have repeatedly requested documents from Debtor but Nelson has not yet provided any documents whatsoever. He has also not yet appeared for the 341(a) meeting, claiming medical issues.

32. I have been informed that unless somebody takes over the patents the applications will expire and the patents will become valueless.

33. My counsel and I have been negotiating with Sweeney for the sale and purchase of the IP since October, 2015. On October 9, 2015, my counsel also inquired of Debtor's counsel whether Debtor's principal, Nelson, was interested in purchasing the IP. No response was received.

34. While I am prepared to accept the offer for the estate's interest in the Assets as set forth above, I am also interested in obtaining the maximum price for the same. Given the unique structure of the proposed sale, I request that the Court authorize me to implement an overbid procedure regarding the sale of the Assets in the manner set forth below.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge, information and belief.

Executed this 29th day of June, 2016 at Los Angeles, California.

AMY L. GOLDMAN, Chapter 7 Trustee

DECLARATION OF ANNIE VERDRIES

I, Annie Verdries, hereby declare as follows:

The following is of my personal knowledge and if called as a witness I could and would competently testify thereto.

1. I am one of the attorneys assigned to handle this matter for Amy L. Goldman as Trustee of the bankruptcy estate ("Trustee").

2. I conducted a search with the United States Patent Office which shows Debtor filed Application Nos. 20100330117 and 20100080826. A true and correct copy of search results are attached hereto as **Exhibit "B."**

3. I conducted a search with the European Patent Office ("EPO") which shows Debtor filed application Nos. EP11769524 and EP08816736. A true and correct copy of search results are attached hereto as **Exhibit "C."**

4. I have received an email from Sweeney which appears to state that Perbil will agree to reduce his claim from $115,000.00 to $15,000.00.

5. I have repeatedly requested documents from Debtor through his counsel but Nelson, Debtor's principal, has not yet provided any documents, except for the Articles of Incorporation. The documents I requested included any documents related to the IP. Debtor has also not yet appeared for the 341(a) meeting, claiming medical issues.

6. I have been informed that unless somebody takes over the patents the applications will expire and the patents will become valueless.

7. I have assisted Trustee with the negotiations with Sweeney for the sale and purchase of the IP since October, 2015. The negotiations were conducted in an arms length transaction. On October 9, 2015, I inquired of Debtor's counsel whether Debtor's principal, Nelson, was interested in purchasing the IP. No response was received. A true and correct copy of my email to Debtor's counsel is attached hereto as **Exhibit "D."**

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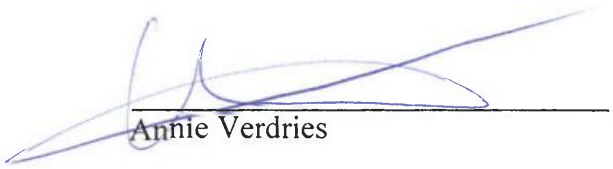
I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this Declaration was executed on June 29, 2016, at Costa Mesa, California.



Annie Verdries

DECLARATION OF JOHN E. SWEENEY

I, JOHN E. SWEENEY, declare as follows:

1. I am an attorney licensed to practice in the State of California, and in all of the Federal Districts of California.

2. I make this declaration of my personal knowledge. If sworn as a witness, I could and would testify competently to each and all of the factual matters set forth herein.

3. When the debtor, Salubrious Pharmaceuticals, LLC, filed its initial Chapter 11 petition on August 15, 2014, I was given notice of the filing, and identified as an unsecured creditor of Salubrious, along with 5 other such creditors. Five of the six scheduled creditors claim a right to an ownership interest promised to them by George Nelson (NELSON), the sole member/manager of Salubrious, as well as substantial monetary obligations owing from Salubrious/Nelson to them. The sixth creditor is owed money, only.

4. The sole asset of the debtor is the collection of patent applications pending before the United States Patent and Trademark Office (USPTO), and the European Patent Office (EPO). The applications were assigned by NELSON to Salubrious in 2010. The most recent iteration of the patent applications seeks protection for the formulation and use, in the treatment of a number of autoimmune diseases, of a combination of long (FDA) approved vaccines. In limited, informal clinical trials involving about 25 patients, very promising results were obtained in the treatment of Rheumatoid Arthritis, Parkinson's, Alzheimer's, Multiple Sclerosis and a few others. I have personal knowledge of the dramatic success of the treatment in 11 of my close friends and acquaintances, suffering variously from the illnesses mentioned. I have the strong conviction that the world will benefit greatly from this treatment if we can save it through the subject offer in Chapter 7.

5. In May 2012, the USPTO rejected the patent application, primarily because the efficacy of the treatment had not been sufficiently shown by the limited trials

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accomplished to that time. The trial patients were few in number for each of the illnesses tested, and the trial was not a double blind study. The rejection noted these inadequacies, and indicated that double blind studies would be required to overcome the rejection by demonstrating efficacy at a meaningful rate. Because Nelson has done nothing, literally, to advance the patent, the pending applications are in danger of expiring, and losing all potential for patent issuance.

6. In 2009, NELSON approached me with an offer to convey to me a 5% member share interest in Salubrious in exchange for my handling several (5) civil litigation matters in which he was involved. These were entirely unrelated to Salubrious, or to the vaccine treatment in any respect. All of these matters were handled by me to conclusion, and I fulfilled all of my obligations in these matters, and to NELSON. Additionally, I had agreed to help NELSON secure the services of a physician to administer the vaccine treatment by way of an informal clinical trial. I then persuaded Chad Wilde, MD, my friend and my wife's physician to undertake the treatment of volunteers afflicted with a variety of illnesses, including those mentioned above. Dr. Wilde died suddenly and very unexpectedly in 2012, delaying what was to be the final submission of supporting data to the Patent Office.

7. NELSON apparently saw Dr. Wilde's death as an opportunity to get out of the promises to convey ownership interests in Salubrious to Dr. Wilde and to myself, as he soon repudiated each of the 5% interests he had promised to convey to each of us. He created similar conflicts with each of the other 4 Creditors who have filed claims in the Chapter 11. All 6 Creditors joined in the Motion to Convert the Chapter 11 to 7. I took this action because NELSON virtually abandoned the patent pursuit, and made no effort to prepare or submit a plan in the Chapter 11 during more than 16 months it was pending. NELSON's inaction, and his outright repudiation of the interests and financial obligations owed to individuals in and out of the bankruptcy, left me and the other Creditors no alternative to making the Motion to Convert, to save the patent project, and preserve a possibility of some repayment of their investments.

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8. Beginning in October 2015, the six creditors commenced their good faith efforts to reach an agreement to acquire the Patent application rights through the Chapter 7. I have led this effort, including the formation of the California limited liability company, Honor C.W. MD, LLC, in which the 6 Creditors have member interests proportionate to their investments and promised equity interests in Salubrious. The offer before the Court is made by this Company.

9. NELSON's lengthy inaction had made the applications pending before the USPTO and in Europe of serious concern. Accordingly, I engaged the services of the very fine Hankin Patent Law firm of Los Angeles to assess the status and viability of the applications, some of which had been pending in one iteration or another since 2008. Hankin did a thorough analysis, presented in a 13 page report. It indicated potential problems with several aspects of the posture of the applications, apart from the simple fact that they were rejected in 2012. NELSON did the absolute minimum to keep them alive to the present time. He alternatively appealed the rejection, and when the appellate brief was due to be filed, he withdrew the appeal and secured what is called a Request For Continuing Examination. At the expiration of the RCE, with nothing done, he withdrew it and filed a new appeal. NELSON has repeated this useless, time-killing sequence 3 times, and is likely at the end of the USPTO rules and tolerance.

10. Our good faith valuation of the patent applications considers their precarious posture, and is based primarily upon the necessary costs of the process in Chapter 7. Of overriding importance is the astronomical future cost facing us, the buyers, in performing the clinical trials of the vaccine treatment needed to demonstrate its efficacy, and thereby achieve patent allowance. This will likely amount to some millions of dollars, and can only be accomplished through help from the team of professionals in medicine and business that I have had standing by for several years. Accordingly, I feel most strongly, that the price we have tendered in this proceeding is fair and just in every respect.

11. It is urgent that the action we contemplate go forward at the earliest

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possible date.

I declare under penalty of perjury under the laws of California and the United States of America, that the foregoing is true and correct. I have executed this Declaration on the 24th day of June, 2016, at Avalon, California.

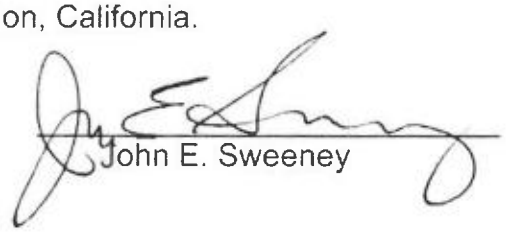

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EXHIBIT A

ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (the "***Agreement***") is made as of June ___ 2016 between AMY L. GOLDMAN (the "***Seller***"), solely in her capacity as Chapter 7 Trustee of the bankruptcy estate (the "***Estate***") of Salubrious Pharmaceutical LLC (the "***Debtor***") and HONOR C.W. M.D., LLC, a California limited liability company (the "***Buyer***").

RECITALS

A. On April 1, 2015 (the "***Petition Date***"), Debtor filed a voluntary petition for relief under Chapter 11 of Title 11 of the United States Code (the "***Bankruptcy Code***") (Case No. 1:15-bk-11118-MT) (the "***Bankruptcy Case***").

B. The Bankruptcy Case was converted to one under Chapter 7 of the Bankruptcy Code pursuant to an order entered on September 9, 2015.

C. Seller is the duly appointed and acting Chapter 7 Trustee of the Debtor's Bankruptcy Case, pending in the United States Bankruptcy Court for the Central District of California, San Fernando Division (the "***Bankruptcy Court***").

D. On September 16, 2015, Debtor filed a notice of appeal of the Bankruptcy Court's order converting the Bankruptcy Case and statement of election to the United States District Court. The United States District Court affirmed the Bankruptcy Court's order on February 10, 2016.

E. Among the potential assets of this Estate known to the Trustee are, without limited, interests in certain pharmaceutical patents, applications for which are pending in, *inter alia,* the European Patent Organization and the United States Patent Office, and related intellectual property (collectively, the "***Assets***").

F. Seller desires to sell to Buyer and Buyer desires to purchase from Seller, the Estate's interests in the Assets on the terms and conditions set forth in this Agreement.

AGREEMENT

NOW THEREFORE, in consideration of the mutual benefits to be derived from this Agreement and the representations, warranties, covenants and agreements contained herein, the Seller and Buyer (collectively, the "***Parties***"), hereby agree as follows:

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1. SALE AND PURCHASE OF ASSETS

1.1 Sale and Purchase of Assets. Subject to the terms and conditions of this Agreement, Seller shall sell, convey, assign, transfer and delivery to Buyer, and Buyer shall purchase, acquire and accept delivery of, the Assets, as is, where is, without any warranty or guaranty, free and clear of any and all pledges, liens, security interests, encumbrances, or other restrictions, if any.

1.2 Assets Defined. The defined term "Assets" as used in this Agreement means, collectively, any and all of Seller's right, title and interest in the pharmaceutical patents, for some of which applications are pending in the European Patent Organization, and other related intellectual property.

1.3 Purchase Price. Subject to the terms and conditions of this Agreement, Buyer agrees to pay the sum of $50,001.00 (the "***Purchase Price***") to Seller, which payment the Seller has received as of the date of this Agreement, by three separate checks in the amount of $16,667 each.

1.4 Subordination of Claims. In addition, some of the principals of Buyer have agreed to subordinate their claims filed in the instant bankruptcy case as set fort in the attached Subordination Agreements.

2. REPRESENTATIONS AND WARRANTIES OF SELLER

Seller hereby represents and warrants to Buyer the following true and accurate statements:

2.1 Authority, Approval, Enforceability. Seller has all requisite power and legal authority to execute and deliver this Agreement, consummate the transaction contemplated hereby and perform his obligations hereunder. Subject to Bankruptcy Court approval, this Agreement, when signed and delivery by Seller, will constitute the legal, valid and binding obligation of Seller, enforceable in accordance with its terms as governed by applicable law and rules. To the knowledge of Seller, the execution, delivery and performance of this Agreement by Seller does not breach any material agreement applicable to Seller.

2.2 Title to Assets. Seller has title to the Assets and has full power and authority to transfer such title to Buyer pursuant to section 363 of the Bankruptcy Code, subject only to Bankruptcy Court approval.

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2.3 Good Faith and Full Disclosure. Prior to Bankruptcy Court approval, Seller will have disclosed to the Bankruptcy Court all material facts known by Seller relating to this Agreement and transaction.

2.4 "As Is" Sale. Seller sells, assigns, transfers and conveys the Assets to Buyer "as is" and "where is," with no representations of warranties.

3. REPRESENTATIONS AND WARRANTIES OF BUYER

3.1 Authority, Approval and Enforceability. Buyer has all requisite power and legal authority to execute and deliver this Agreement and any other documents Buyer is required to execute and deliver hereunder and perform his obligations hereunder. Subject to Bankruptcy Court approval, this Agreement, when signed and delivery by Buyer, will constitute the legal, valid and binding obligation of Seller, enforceable in accordance with its terms as governed by applicable law and rules governing specific performance, injunction and other equitable remedies. To the knowledge of Buyer, the execution, delivery and performance of this Agreement by Buyer does not breach any material agreement applicable to Buyer.

3.2 Good Faith and Full Disclosure. Prior to Bankruptcy Court approval, Buyer will have disclosed to the Bankruptcy Court all material facts known by Buyer relating to this Agreement and transaction. There is no collusion pertaining to this Agreement, and the Buyer is and will remain a good faith purchaser within the meaning of 11 U.S.C. § 363(m). To the best of Buyer's knowledge, there is no action (pending or otherwise) that would prohibit or prevent the transactions contemplated hereby or no basis for the Bankruptcy Court's refusal to approve this Agreement.

4. BANKRUPTCY COURT APPROVAL AND FINAL SALE ORDER

4.1 Motion to Approve Sale. Seller shall file a motion with the Bankruptcy Court, seeking authority to enter into and approve the Agreement. The parties shall exercise all reasonable efforts to cooperate with each other in obtaining a Sale Order.

4.2 Sale Order. The sale of the Assets and the obligations of the parties shall be subject to and conditioned upon approval by the Bankruptcy Court and entry of the Sale Order and such order becoming a final and non-appealable order. The

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Sale Order shall not have been stayed or enjoined by any order of a court with jurisdiction to do so as of the Closing, as defined in Section 7 of this Agreement.

4.3 Final Sale Order. The Final Sale Order is such an order which has not been reversed, stayed, modified or enjoined by any other order of a court with jurisdiction to do so as of the Closing and the time to appeal or move for reconsideration or re-hearing has expired under applicable bankruptcy rules.

5. CONDITIONS TO SELLER'S OBLIGATIONS

5.1 Buyer's Compliance. Buyer shall have complied in all material respects with, and shall have fully performed, the terms, conditions, and obligations of this Agreement to be performed or complied with by Buyer at or prior to the Closing Date, as defined in Section 7 of this Agreement.

5.2 Accuracy of Representations and Warranties. The representations and warranties of Buyer made herein in section 3 hereof shall be true and correct in all material respects, on and as of the Closing Date.

5.3 Payment. Buyer has transferred by check(s), and Seller has received, the total Purchase Price as of the date of this Agreement.

6. CONDITIONS TO BUYER'S OBLIGATIONS

6.1 Accuracy of Representations and Warranties. The representations and warranties of Seller made herein in Section 2 hereof shall be true and correct in all material respects, on and as of the Closing Date.

6.2 Seller's Compliance. Seller have complied in all material respects with, and shall have fully performed, the terms, conditions, and obligations of this Agreement to be performed or complied with by Buyer at or prior to the Closing Date.

6.3 Delivery of Closing Documents. Seller shall have delivered, and Buyer shall have received, all necessary documents to effectuate the transaction contemplated hereby.

7. CLOSING

7.1 Subject to the conditions set forth herein, the consummation of the purchase and sale of the Assets contemplated hereby (the "***Closing***") shall take place on the first business day following the date of the entry of the Final Sale Order (the "***Closing Date***").

7.2 Transfer of Assets; Delivery. At the Closing, title of the Assets shall pass to Buyer and Seller, upon Buyer's request, shall execute and deliver, or cause to be delivered, documents and other instruments of conveyance as shall be reasonably requested by the other party hereto to carry out the transactions contemplated hereby.

8. POST-CLOSING OBLIGATIONS

8.1 Further Assurances. Following the Closing, Seller and Buyer shall execute and deliver such documents, and take such other action, as shall be reasonably requested by the other party hereto to carry out the transaction contemplated by this Agreement.

9. MISCELLANEOUS

9.1 Costs and Expenses. Each of the parties hereto shall bear its own expenses incurred in connection with the negotiation, preparation, execution, and consummation of the transaction contemplated hereby.

9.2 Notices. Any notice, request, instruction, correspondence or other document to be given hereunder by any party hereto to another shall be in writing and shall be mailed by registered or certified mail, postage prepaid and return receipt requested, or by overnight express courier and addressed as follows:

IF TO SELLER:

Amy L. Goldman, Chapter 7 Trustee
633 W. 5th Street, Suite 400
Los Angeles, CA 90071

IF TO BUYER:

Honor C.W. MD, LLC
% John E. Sweeney,
Managing Member
P.O. Box 2721
Avalon, CA 90704-2721

With Copies to:

Annie Verdries
Lewis Brisbois Bisgaard & Smith LLP
650 Town Center Drive, Suite 1400
Costa Mesa, CA 92626
Email: annie.verdries@lewisbrisbois.com

With Copies to:

John E. Sweeney
1197 E. Los Angeles Ave.
Suite C-321
Simi Valley, 93065

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Each of the above addresses for notice purposes may be changed by providing appropriate notice hereunder. Notice given by personal delivery or registered mail shall be effective upon actual receipt. Notice given by telecopier shall be deemed effective two (2) business days after it is sent. Notice by mail is deemed effective three (3) business days after it is deposited in the U.S. Mail. All Notices by telecopier shall be confirmed by the sender thereof promptly after transmission in writing by registered mail or personal delivery. Anything to the contrary contained herein notwithstanding, notices to any party hereto shall not be deemed effective with respect to such party until such Notice would, but for this sentence, be effective both as to such party and as to all other persons to whom copies are provided above to be given.

9.3 Governing Law. This Agreement will be interpreted in accordance with the laws of the State of California and the Bankruptcy Code and applicable Federal Rules of Bankruptcy Procedure.

9.4 Survival. Any provision of this Agreement which contemplates performance or the existence of obligations after the Closing Date, and any and all representations and warranties set forth in this Agreement, shall not be deemed to be merged into or waived by the execution and delivery of the instruments executed at the Closing, but shall expressly survive the Closing and shall be binding upon the party or parties obligated thereby in accordance with the terms of this Agreement.

9.5 Retention of Jurisdiction by Bankruptcy Court. This Agreement shall be subject to the jurisdiction of the Bankruptcy Court. The Bankruptcy Court shall retain jurisdiction to hear and determine any disputes regarding this Agreement or to enforce the terms of this Agreement.

9.6 Entire Agreement; Amendments and Waivers. This Agreement, together with all attachments hereto, the Sale Order, and any other orders of the Bankruptcy Court, constitute the entire agreement between and among the parties hereto pertaining to the subject matter hereof and supersede all prior agreements, understandings, negotiations and discussions, whether oral or written, of the parties, and there are no warranties, representations or other agreements between the parties in connection with the subject matter hereof except as set forth specifically herein or contemplated hereby. No supplement, modification or waiver of this Agreement shall be

binding unless executed in writing signed by Seller and Buyer. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision hereof (regardless of whether similar), nor shall any such waiver constitute a continuing waiver unless otherwise expressly provided.

9.7 Binding Effect and Assignment. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective permitted successors and assigns; but neither this Agreement nor any of the rights, benefits or obligations hereunder shall be assigned, by operation of law or otherwise, by any party hereto without the prior written consent of the other party. Nothing in this Agreement, express or implied, is intended to confer upon any person or entity other than the parties hereto and their respective permitted successors and assigns, any rights, benefits or obligations hereunder.

9.8 Execution in Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

9.9 Attorneys' Fees. In the event of any litigation arising out of this Agreement, the prevailing party shall be entitled to recover from the non-prevailing party its reasonable attorneys, fees and costs.

IN WITNESS WHEREOF, Seller and Buyer executed and delivered this Agreement as of the date first written above.

SELLER	BUYER
AMY L. GOLDMAN, solely in her capacity as Chapter 7 Trustee of the Bankruptcy Estate of Salubrious Pharmaceutical LLC	HONOR C.W. MD, LLC By: John E. Sweeney Its: Managing Member

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EXHIBIT B

US PATENT & TRADEMARK OFFICE

PATENT APPLICATION FULL TEXT AND IMAGE DATABASE

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Searching AppFT Database...

Results of Search in AppFT Database for:
"salubrious pharmaceuticals": 2 applications.
Hits 1 through 2 out of 2

Jump To

Refine Search "salubrious pharmaceuticals"

	PUB. APP. NO.	Title
1	20100330117	PROCESS FOR TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS, RHEUMATOID ARTHRITIS, TREMORS/PARKINSON'S DISEASE, MULTIPLE SCLEROSIS, NON-VIRAL BASED CANCERS, ALZHEIMERS'S DISEASE, MUSCULAR DYSTROPHY, ATTENTION DEFICIT DISORDER, ATTENTION DEFICIT HYPERACTIVITY DISORDER, COMPLEX REGIONAL PAIN SYNDROME, DIABETES, NEUROPATHIC PAIN, SPIDER ARTHRITIS, WEST NILE VIRUS, FIBROMYALGIA, SHINGLES, GOUT, MIGRAINE HEADACHES, SENILE DEMENTIA, POST POLIO SYNDROME, CENTRAL VIRUS DEAFNESS, ASTHMA, CHRONIC PAIN OF UNKNOWN ORIGIN AND HEPATITIS C
2	20100080826	PROCESS FOR TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS, RHEUMATOID ARTHRITIS, TREMORS/PARKINSON'S DISEASE, MULTIPLE SCLEROSIS AND NON-VIRAL BASED CANCERS

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US PATENT & TRADEMARK OFFICE

PATENT APPLICATION FULL TEXT AND IMAGE DATABASE

United States Patent Application 20100330117
Kind Code A1
Nelson; George December 30, 2010

PROCESS FOR TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS, RHEUMATOID ARTHRITIS, TREMORS/PARKINSON'S DISEASE, MULTIPLE SCLEROSIS, NON-VIRAL BASED CANCERS, ALZHEIMERS'S DISEASE, MUSCULAR DYSTROPHY, ATTENTION DEFICIT DISORDER, ATTENTION DEFICIT HYPERACTIVITY DISORDER, COMPLEX REGIONAL PAIN SYNDROME, DIABETES, NEUROPATHIC PAIN, SPIDER ARTHRITIS, WEST NILE VIRUS, FIBROMYALGIA, SHINGLES, GOUT, MIGRAINE HEADACHES, SENILE DEMENTIA, POST POLIO SYNDROME, CENTRAL VIRUS DEAFNESS, ASTHMA, CHRONIC PAIN OF UNKNOWN ORIGIN AND HEPATITIS C

Abstract

The present invention provides a composition and method for treating diseases associated with demyelination of the nerves, such as ALS, RA, Tremors/Parkinson's Disease, and MS, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Tremors/Parkinsons's disease, senile dementia, Muscular Dystrophy, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Complex Regional Pain Syndrome, Diabetes, Neuropathic Pain, Spider Arthritis West Nile Virus, Fibromyalgia, Shingles, Gout, Migraine Headaches, Post Polio Syndrome, Central Virus Deafness, Asthma, Chronic Pain Of Unknown Origin and Hepatitis C and for treating non-viral based cancers. By administering measured doses of an immunity-provoking agent and a bacterial antigen activator, patients suffering from ALS, RA, MS, Tremors/Parkinson's Disease, and prostate cancer and others realized immediate beneficial results with no side effects.

Inventors: **Nelson; George**; *(Woodland Hills, CA)*
Correspondence Address: **DERGOSITS & NOAH LLP**
Three Embarcadero Center, Suite 410
SAN FRANCISCO
CA
94111
US

EXH B PG 29

Assignee: **SALUBRIOUS PHARMACEUTICAL, LLC**
Calabasas
CA

Family ID: **44799012**
Appl. No.: **12/759620**
Filed: **April 13, 2010**

Related U.S. Patent Documents

Application Number	Filing Date	Patent Number
12426838	Apr 20, 2009	
12759620		
12298904	Oct 28, 2008	
PCT/US08/11775	Oct 14, 2008	
12426838		
PCT/US08/11233	Sep 26, 2008	
12298904		

Current U.S. Class: **424/201.1**

Current CPC Class: A61K 35/13 20130101; A61K 39/13 20130101; A61K 2039/54 20130101; A61K 2039/55544 20130101; A61K 2039/70 20130101; C12N 2770/32634 20130101; A61K 39/12 20130101; A61K 2039/5252 20130101; A61K 2039/58 20130101; A61K 2039/6037 20130101

Class at Publication: **424/201.1**

International Class: A61K 39/295 20060101 A61K039/295; A61P 25/28 20060101 A61P025/28; A61P 19/02 20060101 A61P019/02; A61P 25/00 20060101 A61P025/00; A61P 29/00 20060101 A61P029/00; A61P 9/10 20060101 A61P009/10; A61P 25/18 20060101 A61P025/18; A61P 25/16 20060101 A61P025/16; A61P 21/00 20060101 A61P021/00; A61P 3/10 20060101 A61P003/10; A61P 25/04 20060101 A61P025/04; A61P 31/14 20060101 A61P031/14; A61P 31/22 20060101 A61P031/22; A61P 19/06 20060101 A61P019/06; A61P 25/06 20060101 A61P025/06; A61P 43/00 20060101 A61P043/00; A61P 11/06 20060101 A61P011/06; A61P 37/04 20060101 A61P037/04

Foreign Application Data

Date	Code	Application Number
Sep 26, 2008	US	PCTUS08011233

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Oct 14, 2008	US	PCTUS0811775
Nov 12, 2009	US	PCTUS0964238

Claims

1. A composition comprising: (a) 5 parts by volume of an inactivated polio vaccine; and, (b) 2 parts by volume of a bacterial antigen activator selected from the group consisting of tetanus toxoid, typhim VI, diphtheria toxoid and mixtures thereof.

2. The composition of claim 1 packaged for subcutaneous injection.

3. The composition of claim 1 wherein the bacterial antigen activator consists of 1 part by volume tetanus toxoid and 1 part by volume typhim VI.

4. A kit comprising: at least one 70 milliliter dosage of a composition comprising 5 parts by volume of an inactivated polio vaccine, and 2 parts by volume of a bacterial antigen activator selected from the group consisting of tetanus toxoid, typhim IV, diphtheria toxoid and mixtures thereof, packaged for subcutaneous injection.

5. The kit of claim 4 further including instructions for use of the composition in treatment of a disease selected from the group consisting of rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Tremors/Parkinsons's disease, senile dementia, Muscular Dystrophy, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Complex Regional Pain Syndrome, Diabetes, Neuropathic Pain, Spider Arthritis, West Nile Virus, Fibromyalgia, Shingles, Gout, Migraine Headaches, Post Polio Syndrome, Central Virus Deafness, Asthma, Chronic Pain Of Unknown Origin and Hepatitis C.

6. A method for treating pain and inflammation in a patient comprising the steps of: preparing a composition of an inactivated polio vaccine and a bacterial antigen activator selected from the group consisting of tetanus toxoid, typhim VI, diphtheria toxoid and mixtures thereof; and administering the composition to the patient.

7. The method of claim 6, wherein the step of preparing the composition comprises using 5 parts by volume of the inactivated polio vaccine to 2 parts by volume of the bacterial antigen activator.

8. The method of claim 6, wherein the step of preparing the composition comprises using 5 parts by volume of the inactivated polio vaccine to 1 part by volume of the tetanus toxoid and I part by volume of the typhim VI.

9. The method of claim 6, wherein the step of administering the composition comprises administering the composition subcutaneously.

10. The method of claim 6, wherein the step of administering the composition comprises administering approximately 70 mL of the composition.

11. The method of claim 6, wherein the patient is suffering from a disease characterized by demyelination.

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12. The method of claim 11, wherein the disease is selected from the group consisting of rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Parkinsons's disease, senile dementia, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Tremors/Parkinsons's disease, Muscular Dystrophy, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Complex Regional Pain Syndrome, Diabetes, Neuropathic Pain, Spider Arthritis, West Nile Virus, Fibromyalgia, Shingles, Gout, Migraine Headaches, Post Polio Syndrome, Central Virus Deafness, Asthma, Chronic Pain Of Unknown Origin and Hepatitis C.

13. A method for treating ALS in a patient comprising the steps of: preparing a composition of an inactivated polio vaccine and a bacterial antigen activator selected from the group consisting of tetanus toxoid, typhim VI, diphtheria toxoid and mixtures thereof; and administering the composition to the patient.

14. The method of claim 13, wherein the step of preparing the composition comprises using 5 parts by volume of the inactivated polio vaccine to 2 parts by volume of the bacterial antigen activator.

15. The method of claim 14, wherein the step of preparing the composition comprises using 5 parts by volume of the inactivated polio vaccine to 1 part by volume of the tetanus toxoid and 1 part by volume of the typhim VI.

16. The method of claim 15, wherein the step of administering the composition comprises administering the composition subcutaneously.

17. The method of claim 16, wherein the step of administering the composition comprises administering approximately 70 mL of the composition.

18. The method of claim 15, wherein the step of administering the composition comprises administering the composition four times a day.

19. A method for treating pain and inflammation in a patient associated with rheumatoid arthritis comprising the steps of: preparing a composition of an inactivated polio vaccine and a bacterial antigen activator selected from the group consisting of tetanus toxoid, typhim VI, diphtheria toxoid and mixtures thereof; and administering the composition to the patient.

20. The method of claim 19, wherein the step of preparing the composition comprises using 5 parts by volume of the inactivated polio vaccine to 2 parts by volume of the bacterial antigen activator.

21. The method of claim 19, wherein the step of preparing the composition comprises using 5 parts by volume of the inactivated polio vaccine to 1 part by volume of the tetanus toxoid and 1 part by volume of the typhim VI.

22. The method of claim 20, wherein the step of administering the composition comprises administering the composition subcutaneously.

23. The method of claim 22, wherein the step of administering the composition comprises administering approximately 70 mL of the composition.

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Description

RELATED APPLICATION DATA

[0001] This nonprovisional patent application is a continuation in part of U.S. patent application Ser. No. 12/426,838, entitled Process For Treatment Of Amyotrophic Lateral Sclerosis, Rheumatoid Arthritis, Tremors/Parkinson's Disease, Multiple Sclerosis, and Non-Viral Based Cancers, filed Apr. 20, 2009; which is a continuation in part of U.S. patent application Ser. No. 12/298,904, entitled "Process for Treatment of Rheumatoid Arthritis, Tremors/Parkinson's Disease, Multiple Sclerosis and Non-Viral Based Cancers," filed on Oct. 28, 2008; which is the U.S. National Phase application of International Application Serial No. PCT/US08/11775, filed Oct. 14, 2008; which is a continuation in part of International Application Serial No. PCT/US08/011233, entitled Treatment for Rheumatoid Arthritis and Multiple Sclerosis filed Sep. 26, 2008; each of which are incorporated by reference in its entirety.

FIELD

[0002] The present invention relates generally to the treatment of autoimmune disorders, and specifically, to the treatment of demyelinating diseases such as amyotrophic lateral sclerosis, rheumatoid arthritis, Tremors/Parkinson's Disease, multiple sclerosis, Alzheimer's Disease, Muscular Dystrophy, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Complex Regional Pain Syndrome, Diabetes, Neuropathic Pain, Spider Arthritis, West Nile Virus, Fibromyalgia, Shingles, Gout, Migraine Headaches, Senile Dementia, Post Polio Syndrome, Central Virus Deafness, Chronic Pain Of Unknown Origin, Asthma and Hepatitis C. The present invention also relates to the treatment of non-viral based cancers.

BACKGROUND

[0003] Rheumatoid arthritis ("RA") is an autoimmune disease that is typically manifest by inflammation of the synovial joints. The development of RA progresses chronically, alternating between remission and relapse. Damage and deformation of joints can occur rapidly, particularly if the disease is untreated. As the disease progresses, RA can cause joint destruction, functional disability and premature mortality. RA can also include systemic inflammatory disease affecting multiple organs. RA patients often suffer physically and mentally from heavy pain all their lives. The cause of RA is presently unknown.

[0004] As an autoimmune disease, RA is characterized by a defect in the body's ability to distinguish foreign molecules from its own. The immune system attacks the synovial membrane, causing inflammation due to the infiltration of the membrane with T cells, plasma cells and macrophages. Formation of granulation tissue at the edges of the synovial lining is marked by extensive angiogenesis and enzyme production. These effects in turn cause progressive, erosive disintegration of adjacent cartilage and bone. In conjunction with the inflammation of the membranes, patients suffering from RA can also exhibit nerve abnormalities that primarily seem to involve segmental destruction of the myelin sheath.

[0005] Early stage prior art treatments typically attempt to ameliorate the pain symptoms through administration of non-steroidal anti-inflammatory drugs (NSAID). However, these treatments do little

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or nothing to affect the progression of RA.

[0006] Once a definitive RA diagnosis is made, conventional treatments include the use of steroids in conjunction with physical therapy and, if joint damage occurs, surgery. Again, these treatments have significant drawbacks and do not address the underlying causes of RA. For example, steroid therapy is associated with a number of well-known adverse side effects.

[0007] Specific compounds known as disease modifying anti-rheumatic drugs (DMARD) have been developed in an attempt to directly target the processes associated with RA. These DMARDs are typically administered in conjunction with NSAIDs. Examples of such compounds include Remicade.RTM., methotrexate, and Humira.RTM., which are all immunomodulators designed to inhibit the function of the body's immune system. While such treatments can slow the attack of RA, they undermine the ability of the immune system to respond normally to infections and leave the patient vulnerable to other diseases. Furthermore, they do not address the underlying causes of RA. Moreover, there are potentially severe side effects from using these immomodulators and there are restrictions placed on users to avoid exercise, alcohol and to be concerned about drug interferences.

[0008] As no cure for RA exists, there exists a need for treatments that alleviate the pain and inflammation associated with RA without the drawbacks inherent in prior art strategies. Similarly, there is a need for treatments that mitigate the joint damage associated with RA. One object of the current invention is to provide such treatments while minimizing the negative effects on a patient's immune system.

[0009] In addition to RA, there are a number of other progressive or degenerative diseases, such as Crohn's disease, multiple sclerosis ("MS"), Tremors/Parkinson's Disease, Alzheimer's disease, amyotrophic lateral sclerosis ("ALS"), Guillain-Barre syndrome, atherosclerosis, schizophrenia, Parkinsons's disease, senile dementia and others, associated with nerve damage. Although distinct, these diseases share common elements. Specifically, the precise origin or cause of these diseases remains unknown, yet they all exhibit damage to the nerves in the form of demyelination. As with RA, there is currently no cure for these diseases and prior art treatments have focused on modulating the patient's immune system. For example, Copaxone.RTM. is administered to patients suffering from MS in order to suppress immune response. Naturally, a significant side effect of such treatments is the potential for the patient to have a compromised immune system.

[0010] Accordingly, there exists a need for treatments for MS, Alzheimer's disease, Parkinson's disease and the like that minimize the drawbacks associated with the prior art. Similarly, there is a need for a treatment for such diseases that helps prevent demyelination.

[0011] In certain cancers, there may be a latent viral infection that remains quiescent until some signal triggers a release from latency. Once triggered, the tumorous cell begins to replicate. The identification or disease etiology is difficult to assign because in some infections, the DNA of the causation virus is integrated into the genome of the host cell and is transmitted vertically. It therefore behaves as a genetic attribute. In other circumstances, the causative microbe triggers the cancer-disease process and then disappears from the body and is no longer detectable. What is needed, therefore is a vaccine that prevents single strand linear viruses from triggering the release of cancer from latency. It is these types of cancers, such as e.g., prostrate, liver, pancreatic, and lung cancer, that are referred to as the non-viral based cancers. Non-viral based cancers are to be contrasted with viral cancers whose etiology has been directly traced to viral causes. At present, only two viruses, human T-cell lymphotropic virus and human papillomavirus, are considered to be human tumor viruses.

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However, several other candidate viruses are implicated by epidemiological correlation, by serologic relationship or by recovery of virus from tumor cells.

[0012] The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

[0013] The present invention is directed to composition useful in treating symptoms of diseases associated with demyelination of the nerves, such as ALS, RA, MS, Tremors/Parkinson's Disease, non-viral based cancers, Alzheimer's Disease, Muscular Dystrophy, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Complex Regional Pain Syndrome, Diabetes, Neuropathic Pain, Spider Arthritis, West Nile Virus, Fibromyalgia, Shingles, Gout, Migraine Headaches, Senile Dementia, Post Polio Syndrome, Central Virus Deafness, Asthma, Chronic Pain Of Unknown Origin and Hepatitis C. In one embodiment of the invention, the composition includes an immunity-provoking agent and a bacterial antigen activator. Preferably, the immunity-provoking agent is a vaccine for a single-stranded RNA virus and more preferably, the immunity-provoking agent is an inactivated polio vaccine. Also preferably, the bacterial antigen activator is either tetanus toxoid, typhim VI, diphtheria toxoid or mixtures thereof.

[0014] Preferably, the composition comprises 5 parts of the inactivated polio vaccine to 1 part of the tetanus toxoid and 1 part of the typhim VI. Alternatively, the composition comprises 5 parts of the inactivated polio vaccine to 2 parts of either tetanus toxoid, typhim VI, or diphtheria toxoid.

[0015] Also preferably, the composition is formulated for subcutaneous injection.

[0016] Another aspect of the invention is directed to a method for treating pain and inflammation in a patient with one or more of the demyelinating diseases comprising the steps of preparing a composition of an immunity-provoking agent and a bacterial antigen activator; and administering the composition to the patient. Preferably, the step of administering the composition comprises administering the composition subcutaneously. More preferably, the step of administering the composition comprises administering approximately 70 cc of the composition.

[0017] In one embodiment, the method includes treating a patient suffering from a demyelinating disease. Examples of such diseases include rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Tremors/Parkinsons's disease, senile dementia, Alzheimer's Disease, Muscular Dystrophy, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Complex Regional Pain Syndrome, Diabetes, Neuropathic Pain, Spider Arthritis West Nile Virus, Fibromyalgia, Shingles, Gout, Migraine Headaches, Senile Dementia, Post Polio Syndrome, Central Virus Deafness, Asthma, Chronic Pain Of Unknown Origin and Hepatitis C.

[0018] In another embodiment, the method includes treating a patient suffering from a non-viral based cancer disease. Examples of such cancer diseases include prostrate cancers. The treatment of these disease conditions according to the compositions and methods of the invention eliminate the restrictions placed on the user's of prior art immunomodulators and the potentially severe side effects of these compounds.

DETAILED DESCRIPTION

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[0019] The present invention is a process for treating diseases associated with demyelination of the nerves, such as RA, MS, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Tremors/Parkinsons's disease, senile dementia, for treating non-viral based cancers, Alzheimer's Disease, Muscular Dystrophy, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Complex Regional Pain Syndrome, Diabetes, Neuropathic Pain, Spider Arthritis, West Nile Virus, Fibromyalgia, Shingles, Gout, Migraine Headaches, Senile Dementia, Post Polio Syndrome, Central Virus Deafness, Chronic Pain Of Unknown Origin, Asthma and Hepatitis C. By administering measured doses of an immunity-provoking agent and a bacterial antigen activator, patients suffering from these diseases and cancers have realized beneficial results. In connection with the non-viral based cancer diseases, the vaccination should be used, as appropriate, along with surgery, radiation and chemotherapy. However, as a vaccine, the present invention has the ability to combat the genesis of the non-viral cancer disease.

[0020] As discussed above, there exists a significant class of diseases for which the causative agents are poorly understood, but share a common symptom of nerve damage due to demyelination.

[0021] Myelin is the protective sheath around axons in the nervous system, also known as "white matter." Myelin insulates the nerve and facilitates the conduction of the electrical potential associated with a neuronal signal. The myelin sheath is composed of glycolipids and proteins deposited around the axon by glial cells. Myelination of the nerves is an ongoing process that occurs during development and throughout childhood.

[0022] Demyelination can occur when the patient's immune system attacks the sheath, removing portions of the myelin from the axon. The physiological response to this damage causes the formation of gliotic plaques that interfere with conduction of the nerve impulses.

[0023] Without being limited to a particular theory, it is proposed that viral infection causes the patient's myelin to become targeted by the immune system. In response to the infection, the immune system produces antibodies to antigens associated with the infectious agent. However, when these antibodies are insufficiently specific and also recognize normal host antigens, such as components of the myelin sheath, a destructive, autoimmune response can result. Specifically, a dormant childhood infection could form the basis for a subsequent immune response that leads to one of the noted neurodegenerative diseases. Triggers for such a response could be severe physical/psychological trauma or it could be exposure to a suitable antigen or even the natural completion of the myelination process during the transition into adulthood.

[0024] In a related modality, a dormant childhood infection can also form the basis for triggering the replication of cancerous cells that have been in a latent state.

[0025] Accordingly, treatment with a suitable vaccine should counter this effect and compositions of the invention include an immunity-provoking agent.

[0026] Suitable immunity-provoking agents are preparations, such as vaccines, having the ability to confer a degree of immunity to a patient for a demyelinating disease. Preferably, the disease is also known to have the ability to penetrate the central nervous system ("CNS") of the patient.

[0027] In one embodiment of the invention, the immunity-provoking agent comprises a polio vaccine. Poliomyelitis is a disease characterized by degradation of the myelin sheath, often leading to paralysis. The polio virus is a human enterovirus and member of the family of Picornaviridae

composed of a single-stranded positive-sense RNA genome and protein capsid. Although a majority of polio infections are asymptomatic, in a small percentage of cases the virus does invade the patient's CNS, leading to the nerve damage that is the primary symptom of the disease. More preferably, the immunity-provoking agent comprises inactivated polio vaccine ("IPV"), such as trivalent IPV.

[0028] Other suitable uses for this vaccine with the single stranded RNA-based viruses that may be used in the practice of the invention include vaccines for rubella, mumps, measles, Rhinovirus virus, hepatitis A virus, Hepatitis C virus, Yellow Fever Virus, Dengue Virus and West Nile Virus.

[0029] It has been found that the compositions of the invention also require a bacterial antigen activator in conjunction with the immunity-provoking agent. Suitable bacterial antigen activators include gram-negative bacteria vaccines and gram-positive bacteria vaccines. Specific bacterial antigen activators found to be useful in the practice of the invention include tetanus toxoid and typhoid vaccine.

[0030] Clostridium tetani is a gram-positive, obligate anaerobic bacterium that produces the neurotoxin tetanospasmin. Tetanus toxoid is a modified form of tetanospasmin shown to stimulate the production of suitable antibodies and confer an immunity to tetanus. Salmonella enterica serovar typhi is a gram-negative, flagellated, rod-shaped bacterium and is the disease agent in typhoid fever. Typhoid vaccines are prepared from antigens particular to the bacterium. For example, the typhim VI vaccine is prepared from a cell surface polysaccharide of S. typhi.

[0031] The use of Diphtheria Toxoid to develop another vaccine to a single-strand virus is also intended to be within the scope of the invention.

[0032] Accordingly, in a presently preferred embodiment, the subject invention is directed to composition for subcutaneous injection comprising IPV, typhim VI and tetanus toxoid. More specifically, the composition of the invention preferably comprises 1 part tetanus toxoid, 1 part typhim VI, and 5 parts IPV. Alternatively, the composition comprises 2 parts tetanus toxoid and 5 parts IPV. In another alternative, the composition comprises 2 parts typhim VI and 5 parts IPV. In yet another alternative, diphtheria toxoid can be substituted for the tetanus toxoid or for the typhim VI and can be mixed with one or both. The above ratios are all based on concentrations of IPV at (80 D antigen units Type 1)/mL, (16 D antigen units Type 2)/mL, and (64 D antigen units Type 3)/mL, tetanus toxoid at 10 Lf (flocculation units)/mL and 2 units antitoxin/mL, and typhim VI at 50 mg/mL

[0033] The frequency and size of the vaccine dosage can be increased or decreased according to the patient's physical stature, and the general nature of the patient's health. However, preferably, the dosage remains at 70 cc per treatment.

[0034] For treatment in a patient suffering from pain and inflammation, the invention is a method comprising the steps of preparing a composition of immunity-provoking agent and bacterial antigen activator and administering the composition to the patient.

[0035] Preferably, the methods of the invention are directed to treatment of symptoms associated with RA, MS, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Parkinsons's disease, senile dementia, Alzheimer's Disease, Muscular Dystrophy, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Complex Regional Pain Syndrome, Diabetes, Neuropathic Pain, Spider Arthritis, West Nile Virus, Fibromyalgia, Shingles, Gout, Migraine Headaches, Senile Dementia, Post Polio Syndrome, Central Virus Deafness, Chronic Pain Of

Unknown Origin, Asthma and Hepatitis C and other diseases characterized by demyelization, and furthermore to the treatment of non-viral based cancers.

[0036] As noted above, the composition of the method preferably comprises 1 part tetanus toxoid, 1 part typhim VI, and 5 parts IPV, or 2 parts tetanus toxoid and 5 parts IPV, or 2 parts typhim VI and 5 parts IPV. In other embodiments, diphtheria toxoid can be substituted for some or all of the tetanus toxoid or typhim VI.

[0037] Also preferably, the step of administering the composition comprises subcutaneously injecting 70 cc of the composition.

[0038] With regard to subcutaneous administration, the epidermis is composed of 4-5 layers depending on the region of skin being considered. Those layers in descending order are the cornified layer (stratum corneum), clear/translucent layer (stratum lucidum), granular layer (stratum granulosum), spinous layer (stratum spinosum), and basal/germinal layer (stratum hasale/germinativum). The term Malpighian layer (stratum malpighi) refers to both the basal and spinosum layers. When the composition is administered subcutaneously, in a preferred embodiment the syringe should be located in the first, second or third layers, or between first and second layers, or between second and third layers. Once located in these regions, the bolus of the composition is delivered.

A. Case Studies for Rheumatoid Arthritis (RA), Multiple Scleroses (MS), and Tremor's/Parkinson's (P), Prostrate Cancer (PC) and Amyotrophic Lateral Sclerosis (ALS).

[0039] Rheumatoid Arthritis (RA)

[0040] 1. RA is a 61 year old male who has suffered from rheumatoid arthritis in his hands, fingers and back for the last 10 years. He started the medication 5 years ago and within one hour after taking the medication, the pain in his hands, fingers and back disappeared and by the second medication he continued to have no pain and no limitations of movement. He is basically symptom free of his rheumatoid arthritis and has continued taking the medication on a weekly basis. Absolutely no side effects.

[0041] 2. RA is a 63 year old female who gave up golf as a result of rheumatoid arthritis. She has it in her hands, as well as her wrists and believes in her back for 10 years. She started the medication 2 years ago and within 45 minutes after the medication was administered, she was basically pain free, and had full and complete movement of both her wrists, hands and noticed no back pain whatsoever. She takes the medication once every 5 days and continues to remain pain free. Absolutely no side effects.

[0042] 3. RA is a 82 year old man who had severe rheumatoid arthritis for 20 years. For the last 20 years both of his hands were clenched in a fist position and he suffered with severe pain in his hands. He received his first medication 3 years ago. After 45 minutes taking the medication he was crying for joy because this was the first time in 20 years he was without pain and an hour and a half after medication he was able to open his hands one inch. As his treatment continued every 5 days he regained full use of his hands with no pain and absolutely no side effects.

[0043] Multiple Scleroses (MS)

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[0044] 4. MS is a 62 year old female patient who has advanced MS. For eight years she suffered with severe pain in the right leg and was confined to a wheelchair, had incontinence, dysentery and multiple brain sheers (her doctor states that the last time she had seen a patient with this many brain sheers, it was a corpse). She started her medication 21/2 years ago. Her first medication reduced her pain by 50% and the 2.sup.nd medication 2 days later, within 45 minutes had no pain at all. The 3.sup.rd medication 4 days later she was still pain free and was able to stand and use a walker to help her get around. The 4.sup.th medication just 4 days later, she still showed no signs of pain, incontinence or dysentery and had no side effects. She began taking the medication every 5 days to maintain a healthy pain free life still with no dysentery and absolutely no side effects.

[0045] Tremor's/Parkinson's Disease (P)

[0046] 5. P is a 64 year old man who noticed an occasional slight tremor in his left hand one year ago. He thought it was nerves. As time went on, the tremors were more frequent. He consulted with his doctor and was told it was it could be nerves or the beginning of Parkinson's Disease but there was no way to tell without an autopsy (not an option.) He tried compound vitamins, no help. After his first shot of the medication, the tremors stopped within 45 minutes, with no side effects. One week later, the left hand started some movement, I gave him another shot and the movement/tremors stopped. He has taken weekly shots since, and there have been no tremors and no side effects.

[0047] Prostrate Cancer

[0048] 6. Twelve years ago P had a PSA score of 68 and a Gleason score of 7. A radical prostrate ectomy was performed, and P was given a prognosis of one to two years additional life. After P began administering the vaccination of the present invention, P's PSA score was -0.03 and has remained that way for twelve years.

[0049] Amyotrophic Lateral Sclerosis

[0050] 7. YB is a patient that is in the final stages of ALS. She been on various pain medications over the years, but has not realized any significant pain abatement. Prior to receiving the vaccine, YB could not talk, her fingers were locked in a claw-like position, and she suffered from edema in her feet, legs, back and hand. Because of her pain, she was unable to move her jaw, thereby restricting her ability to eat. YB was also restricted from raising her arms above her chest due to the severe pain. In addition, YB suffered from shortness of breath, requiring an oxygen tank for breathing at night.

[0051] Vaccine was administered to YB four times per day. Within five days of continuous treatment, YB experienced significant reduction in her pain and edema. In addition, YB regained the ability to raise her arms and open her jaw. YB no longer needs an oxygen tank at night, and has regained the ability to speak.

B. Case Studies for Muscular Dystrophy, Post Polio Syndrome, West Nile Virus, Fibromyalgia, CRS, Attention Deficit/Hyperactivity Disorder, Neuropathic Pain, Diabetic Neuropathy, Multiple Sclerosis, Chronic Pain, Hepatitis C.

[0052] 1. Complex Regional Pain Syndrome

[0053] LP, 55 year old female, was diagnosed with Reflex Sympathic Dystrophy also known as Complex Regional Pain Syndrome approximately seven years ago. Five years ago LP was also

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diagnosed with gout and shingles. About 10 months ago, LP became 100% deaf in right ear and 30% deaf in left ear, leading to a diagnosis of Viral Central deafness.

[0054] Within 20-30 minutes of administration of the treatment, the patient observed the following effects. Pressure and pain in legs were gone. Ankle and leg swelling were gone as was stabbing pain. Gout in big toe disappeared. Onset of shingles episode reversed. Extreme pressure in right ear relieved. Hearing in left ear clearer. Hearing ability went from monoaural to binaural. Slight hearing in right ear restored (5-10%). Neck pain and stiffness were gone, and LP had the restoration of complete range of motion in her neck; headache also relieved. Feet pain completely relieved, restoring ability to walk normally.

[0055] 2. Muscular Dystrophy

[0056] Male Age 42 with Muscular Dystrophy contracted the disease at age 16. Patient exhibited bad balance and difficulty walking without a cane. He experienced chronic pain in his legs, back and arms. Two hours after first treatment, the patient said that the pain was gone, the tightness in his legs and arms was gone and he could walk easily with no pain or other problems.

[0057] 3. Post Polio Syndrome

[0058] Male Age 79 with Post Polio Syndrome contracted polio at age 6, recovered and was doing fine until four years ago when he exhibited symptoms of Post Polio Syndrome, giving him weakening of the muscles, fatigue, pain in the muscles and joints, shortness of breath and sleeping problems. Within one hour of the treatment, the pain was gone. After two hours, he felt new energy and was walking easier and breathing better, with no side effects from the treatment.

[0059] 4. West Nile Virus

[0060] Female Age 35 with West Nile Virus complained of pain in her eyes, headaches and muscle and stomach pain. Within two hours of treatment, she was pain free and her condition continued to improve with no side effects.

[0061] 5. Fibromyalgia

[0062] 30 Year Old Female with Fibromyalgia had pain throughout her body, aching and fatigue; she experienced slight swelling of the muscles, headaches and numbness and tingling of the extremities. After her first treatment, she was pain free within one hour and continued to improve with no side effects.

[0063] 6. Attention Deficit/Hyperactivity Disorder

[0064] Male patient age 59 diagnosed with AD/HD at age 55. Patient stopped AD/HD medications forty-eight hours before treatment. Within one hour of treatment, patient was observed to be calmer, which lasted for approximately seven days. Patient experienced an overall evenness in his nature and thoughts. Normal stress factors did not have usual negative result. Patient felt that he had his normal energy level without ups and downs associated with the AD/HD medications he had been taking for several years.

[0065] 7. Neuropathic pain of Mixed Etiology including Diabetic Neuropathy, Multiple Sclerosis and

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Lumbar Radiculopathy

[0066] This involves utilizing two patients data together and meshing the information. The parties were middle aged males. One had a history of neuropathic pain extending from questionably some vitamin induced neurpathic pain or lack thereof of vitamins, lumbar radiopathy from disc bulges, facet hypertrophy, joint pain, and shooting sciatica pain down the legs. The other patient had nerve pain into the feet and leg bilaterally from multiple sclerosis and had undergone standard therapies with multiple sclerosis medications having serious side effects. He then underwent a month's treatment of the medication from ***Salubrious Pharmaceuticals*** LLC.

[0067] Treatment began with the single arm protocol and increase to dual arm protocol on a second visit and then increased the dosage on the third visit. Between the third and fourth visit the dose was maintained. Ultimately, the final dose was 80 IPV/40 B.A. per arm. Both patients did very well and had over 75% improvement in their pain function. The patient with radiculopathy from the disc bulge, facet hypertrophy and lack of vitamins had improved ability to walk, improved sensation of the ground with the foot as if he can curl his toes and feel where he was going. His balance improved and felt good throughout the entire process. His head was clear. He moved and walked better. He had no falls which had been an issue in the past. He had improved urinary continence and the ability to control bladder and bowel function.

[0068] The second patient had significant improvement in his bladder and bowel function. He did not have a significant effect on the nerve pain. However, patient was able to sleep better and overall felt much better. He had no feelings of flare-up or need for any types of muscular dystrophy medications. All of his medications were stopped for twelve weeks. There were no steroids given during that time and the patient felt good. He was able to get into a regimen of exercise on a daily program and overall was feeling better.

[0069] Both patients seem to respond favorably during the one month trial and there were no side effects noted.

[0070] 8. Chronic Pain of Unknown Origin

[0071] PT is a 43 year old female with pain of unknown origin. She has multiple other medical comorbidities but has not clearly ascertained an underlying cause for her self-reported levels of pain. The pain is very severe which has necessitated high doses of opiates of which she has poorly responded. The pain has been in different areas and it rotates between the abdomen, back, neck, hips and joints. She has not had one particular protocol even any subtype RSD or fibromyalgia. A number of diagnostic codes have been used including fibromyalgia, causalgia/RSD, mononeuritis, radiculopathy, DDD, DJD, associated myalgias, headaches, chronic fatigue syndrome and a number of other diagnostic codes to allow for us to try to work up some of her underlying issues but ultimately there has not been any clear cause for anything.

[0072] She came in for the trial and was given a double dose, one in each arm. She did very well and within one hour she felt the pain go away. She described it as when she was younger she had a migraine and was given Imitrex at the hospital (or some shot at the hospital which she believe was Imitrex now). Patient states that it felt like crackling. The pain crackled and went away very quickly. Within one hour she said the pain was decreased by over 75%. She had effect that lasted beyond one week. However, at nearly one week mark she said the pain started to come back more frequently and she started to develop a lot of the symptoms that she started in the beginning which were difficulty

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with sleep, some memory deficits and some other secondary side effects with agitation.

[0073] We are still awaiting a functional MRI on this patient and a PET scan to see if possibly there was ever a stroke. A central post pain syndrome has been of the potential ideas as her underlying cause. However, from the changes in the pair so frequently, there must have been an emotional component. She has had a lot of stress in her life. The most important aspect is that she had no side effects to the study drug from ***Salubrious Pharmaceuticals*** and had an amazing improvement during that week. At the end she asked how she could continue to get the medication because it changed her life so much.

[0074] 9. Hepatitis C

[0075] Discussion with a female patient who has Hepatitis C and a number of other medical comorbidities that had a very aggressive history of drug abuse as a child and many other medical conditions that are not clear. The only etiological origin of her pain is she has cervical DDD, cervical DJD, and extreme myalgias. She had undergone trigger point injections, epidurals, nerve blocks, facet joint blocks, many other adjuvant therapies, chiropractic care, alternative medicine with some other practitioners, vitamin and mineral supplementation. She had contracted Hepatitis C while doing drugs in her youth but had a flare up of the hepatitis C approximately two years ago. She was treated with Interferon and Ribavirin and had weekly injections which made her very sick. She lost a lot of her energy and had very little ability to function. She ultimately needed to go on medical leave because of the amount of pain that she was having. She was asked to get viral loads and Hepatitis panels prior to testing. She was not able to afford it but went out and got some labs done. She was not sure where results were sent. Treating physician did not receive copies of lab reports.

[0076] Her first injection was at the normal dose in one arm. She noticed an improvement in her pain and felt as if things were melting inside of her. She felt uneasiness but within a short period of time she started to feel a little bit better. Within the next four to five days, she felt much better. Her pain medication was too strong for her and she was surprised how well it was working and actually needed to decrease it. She said she felt like the ***Salubrious Pharmaceuticals*** medication wore off on her and did not last long enough. It lasted five days or so and then started to wear off. She came back to the physician after the seven day mark and was given a follow up injection. This time she was given a double dose in each arm. She felt immediate response within one hour with significant improvement. Overall, it made significant improvement in the quality of her life.

[0077] 10. Alzheimer's Disease

[0078] Female patient SN, aged 82, was diagnosed with Alzheimer's disease in 2006 after a very stressful life event. She had decreasing mental function, such that her husband stated that he needed to take steps to help her memory everywhere around the house. For example, white out was placed on the toaster over to help her know which buttons to push to cook. When treating physician met SN she could not recall her marriage date and multiple other facts about her life. One hour after giving SN the treatment, she was able to recall answers to questions that came from both short term and long term memory. The questions were asked once, and some of the questions were over materials that the treating physician had presented to her or asked her about one hour before administering treatment. SN's daughter and husband were present, and they observed that she had made an enormous memorable improvement. SN was smiling, happy, her demeanor was filled with joy and happiness. Treating physician was astonished at the speed of her response to the treatment and her improved ability to respond to the treating physician's questions. She was asked questions about her articles of

clothing, the treating physician's recitation of the side effects and her wedding date, all of which she was able to answer after treatment.

[0079] 11. Alzheimer's Disease

[0080] Male patient JM age 73 has been afflicted with Alzheimer's disease for several years. He has progressively lost his ability to reason, calculate and plan. He has been afflicted with hallucinations where he will talk to pictures on the wall as if communicating with the person pictured. Similarly, he will speak to persons on television in similar fashion.

[0081] JM received an injection of the treatment in each arm. Subsequent to receiving the treatment, after about an hour, JM was able to count backwards from 10 to 1, without much hesitation. This was an exercise he had wholly failed to perform before the treatment. Additionally, he managed some identification of events in his past such as date of birth, and memories from previous employment. He was observed to act in a more involved and coherent manner than in recent past. He was able to recall the specific details of conversations that had occurred 27 hours prior.

[0082] One will appreciate that in the description above and throughout, numerous specific details are set forth in order to provide a thorough understanding of the present invention. It will be evident, however, to one of ordinary skill in the art, that the present invention may be practiced without these specific details. In other instances, well-known structures and devices are shown in block diagram form to facilitate explanation. The description of the preferred embodiments is not intended to limit the scope of the claims appended hereto.

* * * * *

EXH B PG 43

US PATENT & TRADEMARK OFFICE

PATENT APPLICATION FULL TEXT AND IMAGE DATABASE

United States Patent Application 20100080826
Kind Code A1
Nelson; George April 1, 2010

PROCESS FOR TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS, RHEUMATOID ARTHRITIS, TREMORS/PARKINSON'S DISEASE, MULTIPLE SCLEROSIS AND NON-VIRAL BASED CANCERS

Abstract

The present invention provides a composition and method for treating diseases associated with demyelination of the nerves, such as ALS, RA, Tremors/Parkinson's Disease, and MS, and for treating non-viral based cancers. By administering measured doses of an immunity-provoking agent and a bacterial antigen activator, patients suffering from ALS, RA, MS, Tremors/Parkinson's Disease, and prostrate cancer realized immediate beneficial results with no side effects.

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Family ID: **43011385**
Appl. No.: **12/426838**
Filed: **April 20, 2009**

Related U.S. Patent Documents

EXH B PG 44

Application Number	Filing Date	Patent Number
12298904		
PCT/US08/11775	Oct 14, 2008	
12426838		
PCT/US08/11233	Sep 26, 2008	
12298904		

Current U.S. Class:	**424/204.1**
Current CPC Class:	A61K 39/13 20130101; A61K 2039/54 20130101; A61K 2039/6037 20130101; C12N 2770/32634 20130101; A61K 39/05 20130101; A61K 2039/5252 20130101; A61K 2039/58 20130101; A61K 2039/70 20130101; A61K 39/0275 20130101; A61K 39/08 20130101; A61K 39/12 20130101
Class at Publication:	**424/204.1**
International Class:	A61K 39/13 20060101 A61K039/13; A61P 37/04 20060101 A61P037/04

Claims

1. A composition comprising an immunity-provoking agent and a bacterial antigen activator.

2. The composition of claim 1, wherein the immunity-provoking agent comprises a vaccine for a single-stranded RNA-based virus.

3. The composition of claim 2, wherein the immunity-provoking agent comprises an inactivated polio vaccine.

4. The composition of claim 1, wherein at least one bacterial antigen activator is selected from the group comprising tetanus toxoid and typhim VI.

5. The composition of claim 3, wherein the bacterial antigen activator is selected from the group comprising tetanus toxoid and typhim VI.

6. The composition of claim 5, further comprising 5 parts of the inactivated polio vaccine to 2 parts of the bacterial antigen activator.

7. The composition of claim 5, further comprising 5 parts of the inactivated polio vaccine to 1 part of the tetanus toxoid and 1 part of the typhim VI.

8. The composition of claim 1, wherein the composition is formulated for subcutaneous injection.

9. A method for treating pain and inflammation in a patient comprising the steps of: preparing a composition of an immunity-provoking agent and a bacterial antigen activator; and administering the

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composition to the patient.

10. The method of claim 9, wherein the step of preparing the composition comprises using a vaccine for a single-stranded RNA-based virus for the immunity-provoking agent.

11. The method of claim 10, wherein the step of preparing the composition comprises using inactivated polio vaccine for the immunity-provoking agent.

12. The method of claim 11, wherein the step of preparing the composition comprises using at least one bacterial antigen activator selected from the group comprising tetanus toxoid and typhim VI.

13. The method of claim 12, wherein the step of preparing the composition comprises using 5 parts of the inactivated polio vaccine to 2 parts of the bacterial antigen activator.

14. The method of claim 12, wherein the step of preparing the composition comprises using 5 parts of the inactivated polio vaccine to 1 part of the tetanus toxoid and 1 part of the typhim VI.

15. The method of claim 9, wherein the step of administering the composition comprises administering the composition subcutaneously.

16. The method of claim 15, wherein the step of administering the composition comprises administering approximately 70 mL of the composition.

17. The method of claim 9, wherein the patient is suffering from a disease characterized by demyelination.

18. The method of claim 17, wherein the disease is selected from the group consisting of rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Parkinsons's disease, and senile dementia.

19. A method for treating ALS in a patient comprising the steps of: preparing a composition of an immunity-provoking agent and a bacterial antigen activator; and administering the composition to the patient.

20. The method of claim 19, wherein the step of preparing the composition comprises using a vaccine for a single-stranded RNA-based virus for the immunity-provoking agent.

21. The method of claim 20, wherein the step of preparing the composition comprises using inactivated polio vaccine for the immunity-provoking agent.

22. The method of claim 21, wherein the step of preparing the composition comprises using at least one bacterial antigen activator selected from the group comprising tetanus toxoid and typhim VI.

23. The method of claim 22, wherein the step of preparing the composition comprises using 5 parts of the inactivated polio vaccine to 2 parts of the bacterial antigen activator.

24. The method of claim 22, wherein the step of preparing the composition comprises using 5 parts of the inactivated polio vaccine to 1 part of the tetanus toxoid and 1 part of the typhim VI.

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25. The method of claim 19, wherein the step of administering the composition comprises administering the composition subcutaneously.

26. The method of claim 25, wherein the step of administering the composition comprises administering approximately 70 mL of the composition.

27. The method of claim 19, wherein the step of administering the composition comprises administering the composition four times a day.

Description

RELATED APPLICATION DATA

[0001] This nonprovisional patent application is a continuation in part of U.S. patent application Ser. No. 12/298,904, entitled "Process for Treatment of Rheumatoid Arthritis, Tremors/Parkinson's Disease, Multiple Sclerosis and Non-Viral Based Cancers," filed on Oct. 28, 2008; which is the U.S. National Phase application of International Application Serial No. PCT/U.S.08/11775, filed Oct. 14, 2008; each of which are incorporated by reference in its entirety.

FIELD

[0002] The present invention relates generally to the treatment of autoimmune disorders, and specifically, to the treatment of demyelinating diseases such as amyotrophic lateral sclerosis, rheumatoid arthritis, Tremors/Parkinson's Disease and multiple sclerosis. The present invention also relates to the treatment of non-viral based cancers.

BACKGROUND

[0003] Rheumatoid arthritis ("RA") is an autoimmune disease that is typically manifest by inflammation of the synovial joints. The development of RA progresses chronically, alternating between remission and relapse. Damage and deformation of joints can occur rapidly, particularly if the disease is untreated. As the disease progresses, RA can cause joint destruction, functional disability and premature mortality. RA can also include systemic inflammatory disease affecting multiple organs. RA patients often suffer physically and mentally from heavy pain all their lives. The cause of RA is presently unknown.

[0004] As an autoimmune disease, RA is characterized by a defect in the body's ability to distinguish foreign molecules from its own. The immune system attacks the synovial membrane, causing inflammation due to the infiltration of the membrane with T cells, plasma cells and macrophages. Formation of granulation tissue at the edges of the synovial lining is marked by extensive angiogenesis and enzyme production. These effects in turn cause progressive, erosive disintegration of adjacent cartilage and bone. In conjunction with the inflammation of the membranes, patients suffering from RA can also exhibit nerve abnormalities that primarily seem to involve segmental destruction of the myelin sheath.

[0005] Early stage prior art treatments typically attempt to ameliorate the pain symptoms through administration of non-steroidal anti-inflammatory drugs (NSAID). However, these treatments do little

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or nothing to affect the progression of RA.

[0006] Once a definitive RA diagnosis is made, conventional treatments include the use of steriods in conjunction with physical therapy and, if joint damage occurs, surgery. Again, these treatments have significant drawbacks and do not address the underlying causes of RA. For example, steroid therapy is associated with a number of well-known adverse side effects.

[0007] Specific compounds known as disease modifying anti-rheumatic drugs (DMARD) have been developed in an attempt to directly target the processes associated with RA. These DMARDs are typically administered in conjunction with NSAIDs. Examples of such compounds include Remicade.RTM., methotrexate, and Humira.RTM., which are all immunomodulators designed to inhibit the function of the body's immune system. While such treatments can slow the attack of RA, they undermine the ability of the immune system to respond normally to infections and leave the patient vulnerable to other diseases. Furthermore, they do not address the underlying causes of RA. Moreover, there are potentially severe side effects from using these immomodulators and there are restrictions placed on users to avoid exercise, alcohol and to be concerned about drug interferences.

[0008] As no cure for RA exists, there exists a need for treatments that alleviate the pain and inflammation associated with RA without the drawbacks inherent in prior art strategies. Similarly, there is a need for treatments that mitigate the joint damage associated with RA. One object of the current invention is to provide such treatments while minimizing the negative effects on a patient's immune system.

[0009] In addition to RA, there are a number of other progressive or degenerative diseases, such as Crohn's disease, multiple sclerosis ("MS"), Tremors/Parkinson's Disease, Alzheimer's disease, amyotrophic lateral sclerosis ("ALS"), Guillain-Barre syndrome, atherosclerosis, schizophrenia, Parkinsons's disease, senile dementia and others, associated with nerve damage. Although distinct, these diseases share common elements. Specifically, the precise origin or cause of these diseases remains unknown, yet they all exhibit damage to the nerves in the form of demyelination. As with RA, there is currently no cure for these diseases and prior art treatments have focussed on modulating the patient's immune system. For example, Copaxone.RTM. is administered to patients suffering from MS in order to suppress immune response. Naturally, a significant side effect of such treatments is the potential for the patient to have a compromised immune system.

[0010] Accordingly, there exists a need for treatments for MS, Alzheimer's disease, Parkinson's disease and the like that minimize the drawbacks associated with the prior art. Similarly, there is a need for a treatment for such diseases that helps prevent demyelination.

[0011] In certain cancers, there may be a latent viral infection that remains quiescent until some signal triggers a release from latency. Once triggered, the tumorous cell begins to replicate. The identification or disease etiology is difficult to assign because in some infections, the DNA of the causation virus is integrated into the genome of the host cell and is transmitted vertically. It therefore behaves as a genetic attribute. In other circumstances, the causative microbe triggers the cancer-disease process and then disappears from the body and is no longer detectable. What is needed, therefore is a vaccine that prevents single strand linear viruses from triggering the release of cancer from latency. It is these types of cancers, such as e.g., prostrate, liver, pancreatic, and lung cancer, that are referred to as the non-viral based cancers. Non-viral based cancers are to be contrasted with viral cancers whose etiology has been directly traced to viral causes. At present, only two viruses, human T-cell lymphotropic virus and human papillomavirus, are considered to be human tumor viruses.

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However, several other candidate viruses are implicated by epidemiological correlation, by serologic relationship or by recovery of virus from tumor cells.

[0012] The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

[0013] The present invention is directed to composition useful in treating symptoms of diseases associated with demyelination of the nerves, such as ALS, RA, MS, Tremors/Parkinson's Disease and non-viral based cancers. In one embodiment of the invention, the composition includes an immunity-provoking agent and a bacterial antigen activator. Preferably, the immunity-provoking agent is a vaccine for a single-stranded RNA virus and more preferably, the immunity-provoking agent is an inactivated polio vaccine. Also preferably, the bacterial antigen activator is either or both tetanus toxoid and typhim VI.

[0014] Preferably, the composition comprises 5 parts of the inactivated polio vaccine to 1 part of the tetanus toxoid and 1 part of the typhim VI. Alternatively, the composition comprises 5 parts of the inactivated polio vaccine to 2 parts of either tetanus toxoid or typhim VI.

[0015] Also preferably, the composition is formulated for subcutaneous injection.

[0016] Another aspect of the invention is directed to a method for treating pain and inflammation in a patient comprising the steps of preparing a composition of an immunity-provoking agent and a bacterial antigen activator; and administering the composition to the patient. Preferably, the step of administering the composition comprises administering the composition subcutaneously. More preferably, the step of administering the composition comprises administering approximately 70 cc of the composition.

[0017] In one embodiment, the method includes treating a patient suffering from a demyelinating disease. Examples of such diseases include rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Tremors/Parkinsons's disease, and senile dementia.

[0018] In another embodiment, the method includes treating a patient suffering from a non-viral based cancer disease. Examples of such cancer diseases include prostrate cancers. The treatment of these disease conditions according to the compositions and methods of the invention eliminate the restrictions placed on the user's of prior art immunomodulators and the potentially severe side effects of these compounds.

DETAILED DESCRIPTION

[0019] The present invention is a process for treating diseases associated with demyelination of the nerves, such as RA, MS, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Tremors/Parkinsons's disease, and senile dementia, and for treating non-viral based cancers. By administering measured doses of an immunity-provoking agent and a bacterial antigen activator, patients suffering from these diseases and cancers have realized beneficial results. In connection with the non-viral based cancer diseases, the vaccination should be used, as appropriate, along with surgery, radiation and chemotherapy. However, as a vaccine, the present invention has the ability to combat the genesis of the non-viral cancer disease.

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[0020] As discussed above, there exists a significant class of diseases for which the causative agents are poorly understood, but share a common symptom of nerve damage due to demyelination.

[0021] Myelin is the protective sheath around axons in the nervous system, also known as "white matter." Myelin insulates the nerve and facilitates the conduction of the electrical potential associated with a neuronal signal. The myelin sheath is composed of glycolipids and proteins deposited around the axon by glial cells. Myelination of the nerves is an ongoing process that occurs during development and throughout childhood.

[0022] Demyelination can occur when the patient's immune system attacks the sheath, removing portions of the myelin from the axon. The physiological response to this damage causes the formation of gliotic plaques that interfere with conduction of the nerve impulses.

[0023] Without being limited to a particular theory, it is proposed that viral infection causes the patient's myelin to become targeted by the immune system. In response to the infection, the immune system produces antibodies to antigens associated with the infectious agent. However, when these antibodies are insufficiently specific and also recognize normal host antigens, such as components of the myelin sheath, a destructive, autoimmune response can result. Specifically, a dormant childhood infection could form the basis for a subsequent immune response that leads to one of the noted neurodegenerative diseases. Triggers for such a response could be severe physical/psychological trauma or it could be exposure to a suitable antigen or even the natural completion of the myelination process during the transition into adulthood.

[0024] In a related modality, a dormant childhood infection can also form the basis for triggering the replication of cancerous cells that have been in a latent state.

[0025] Accordingly, treatment with a suitable vaccine should counter this effect and compositions of the invention include an immunity-provoking agent.

[0026] Suitable immunity-provoking agents are preparations, such as vaccines, having the ability to confer a degree of immunity to a patient for a demyelinating disease. Preferably, the disease is also known to have the ability to penetrate the central nervous system ("CNS") of the patient.

[0027] In one embodiment of the invention, the immunity-provoking agent comprises a polio vaccine. Poliomyelitis is a disease characterized by degradation of the myelin sheath, often leading to paralysis. The polio virus is a human enterovirus and member of the family of Picornaviridae composed of a single-stranded positive-sense RNA genome and protein capsid. Although a majority of polio infections are asymptomatic, in a small percentage of cases the virus does invade the patient's CNS, leading to the nerve damage that is the primary symptom of the disease. More preferably, the immunity-provoking agent comprises inactivated polio vaccine ("IPV"), such as trivalent IPV.

[0028] Other suitable uses for this vaccine with the single stranded RNA-based viruses that may be used in the practice of the invention include vaccines for rubella, mumps, measles, Rhinovirus virus, hepatitis A virus, Hepatitis C virus, Yellow Fever Virus, Dengue Virus and West Nile Virus.

[0029] It has been found that the compositions of the invention also require a bacterial antigen activator in conjunction with the immunity-provoking agent. Suitable bacterial antigen activators include gram-negative bacteria vaccines and gram-positive bacteria vaccines. Specific bacterial

EXH B PG 50

antigen activators found to be useful in the practice of the invention include tetanus toxoid and typhoid vaccine.

[0030] Clostridium tetani is a gram-positive, obligate anaerobic bacterium that produces the neurotoxin tetanospasmin. Tetanus toxoid is a modified form of tetanospasmin shown to stimulate the production of suitable antibodies and confer an immunity to tetanus. Salmonella enierica serovar typhi is a gram-negative, flagellated, rod-shaped bacterium and is the disease agent in typhoid fever. Typhoid vaccines are prepared from antigens particular to the bacterium. For example, the typhim VI vaccine is prepared from a cell surface polysaccharide of S. typhi.

[0031] The use of Diphtheria Toxoid to develop another vaccine to a single-strand virus is also intended to be within the scope of the invention.

[0032] Accordingly, in a presently preferred embodiment, the subject invention is directed to composition for subcutaneous injection comprising IPV, typhim VI and tetanus toxoid. More specifically, the composition of the invention preferably comprises 1 part tetanus toxoid, 1 part typhim VI, and 5 parts IPV. Alternatively, the composition comprises 2 parts tetanus toxoid and 5 parts IPV. In another alternative, the composition comprises 2 parts typhim VI and 5 parts IPV. The above ratios are all based on concentrations of IPV at (80 D antigen units Type 1)/mL, (16 D antigen units Type 2)/mL, and (64 D antigen units Type 3)/mL, tetanus toxoid at 10 Lf (flocculation units)/mL and 2 units antitoxin/mL, and typhim VI at 50 mg/mL.

[0033] The frequency and size of the vaccine dosage can be increased or decreased according to the patient's physical stature, and the general nature of the patient's health. However, preferably, the dosage remains at 70 cc per treatment.

[0034] For treatment in a patient suffering from pain and inflammation, the invention is a method comprising the steps of preparing a composition of immunity-provoking agent and bacterial antigen activator and administering the composition to the patient.

[0035] Preferably, the methods of the invention are directed to treatment of symptoms associated with RA, MS, Alzheimer's disease, ALS, Guillain-Barre syndrome, atherosclerosis, schizophrenia, Parkinsons's disease, senile dementia, and other diseases characterized by demyelization, and furthermore to the treatment of non-viral based cancers.

[0036] As noted above, the composition of the method preferably comprises 1 part tetanus toxoid, 1 part typhim VI, and 5 parts IPV, or 2 parts tetanus toxoid and 5 parts IPV, or 2 parts typhim VI and 5 parts IPV.

[0037] Also preferably, the step of administering the composition comprises subcutaneously injecting 70 cc of the composition.

A. Case Studies for Rheumatoid Arthritis (RA), Multiple Scleroses (MS), and Tremor's/Parkinson's (P), Prostrate Cancer (PC) and Amyotrophic Lateral Sclerosis (ALS).

[0038] Rheumatoid Arthritis (RA)

[0039] 1. RA is a 61 year old male who has suffered from rheumatoid arthritis in his hands, fingers and back for the last 10 years. He started the medication 5 years ago and within one hour after taking

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the medication, the pain in his hands, fingers and back disappeared and by the second medication he continued to have no pain and no limitations of movement. He is basically symptom free of his rheumatoid arthritis and has continued taking the medication on a weekly basis. Absolutely no side effects.

[0040] 2. RA is a 63 year old female who gave up golf as a result of rheumatoid arthritis. She has it in her hands, as well as her wrists and believes in her back for 10 years. She started the medication 2 years ago and within 45 minutes after the medication was administered, she was basically pain free, and had full and complete movement of both her wrists, hands and noticed no back pain whatsoever. She takes the medication once every 5 days and continues to remain pain free. Absolutely no side effects.

[0041] 3. RA is a 82 year old man who had severe rheumatoid arthritis for 20 years. For the last 20 years both of his hands were clenched in a fist position and he suffered with severe pain in his hands. He received his first medication 3 years ago. After 45 minutes taking the medication he was crying for joy because this was the first time in 20 years he was without pain and an hour and a half after medication he was able to open his hands one inch. As his treatment continued every 5 days he regained full use of his hands with no pain and absolutely no side effects.

[0042] Multiple Scleroses (MS)

[0043] MS is a 62 year old female patient who has advanced MS. For eight years she suffered with severe pain in the right leg and was confined to a wheelchair, had incontinence, dysentery and multiple brain sheers (her doctor states that the last time she had seen a patient with this many brain sheers, it was a corpse). She started her medication 21/2 years ago. Her first medication reduced her pain by 50% and the 2.sup.nd medication 2 days later, within 45 minutes had no pain at all. The 3.sup.rd medication 4 days later she was still pain free and was able to stand and use a walker to help her get around. The 4.sup.th medication just 4 days later, she still showed no signs of pain, incontinence or dysentery and had no side effects. She began taking the medication every 5 days to maintain a healthy pain free life still with no dysentery and absolutely no side effects.

[0044] Tremor's/Parkinson's Disease (P)

[0045] P is a 64 year old man who noticed an occasional slight tremor in his left hand one year ago. He thought it was nerves. As time went on, the tremors were more frequent. He consulted with his doctor and was told it was it could be nerves or the beginning of Parkinson's Disease but there was no way to tell without an autopsy (not an option.) He tried compound vitamins, no help. After his first shot of the medication, the tremors stopped within 45 minutes, with no side effects. One week later, the left hand started some movement, I gave him another shot and the movement/tremors stopped. He has taken weekly shots since, and there have been no tremors and no side effects.

[0046] Prostrate Cancer

[0047] Twelve years ago P had a PSA score of 68 and a Gleason score of 7. A radical prostrate ectomy was performed, and P was given a prognosis of one to two years additional life. After P began administering the vaccination of the present invention, P's PSA score was -0.03 and has remained that way for twelve years.

[0048] Amyotrophic Lateral Sclerosis

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[0049] YB is a patient that is in the final stages of ALS. She been on various pain medications over the years, but has not realized any significant pain abatement. Prior to receiving the vaccine, YB could not talk, her fingers were locked in a claw-like position, and she suffered from edema in her feet, legs, back and hand. Because of her pain, she was unable to move her jaw, thereby restricting her ability to eat. YB was also restricted from raising her arms above her chest due to the severe pain. In addition, YB suffered from shortness of breath, requiring an oxygen tank for breathing at night.

[0050] Vaccine was administered to YB four times per day. Within five days of continuous treatment, YB experienced significant reduction in her pain and edema. In addition, YB regained the ability to raise her arms and open her jaw. YB no longer needs an oxygen tank at night, and has regained the ability to speak.

[0051] One will appreciate that in the description above and throughout, numerous specific details are set forth in order to provide a thorough understanding of the present invention. It will be evident, however, to one of ordinary skill in the art, that the present invention may be practiced without these specific details. In other instances, well-known structures and devices are shown in block diagram form to facilitate explanation. The description of the preferred embodiments is not intended to limit the scope of the claims appended hereto.

* * * * *

EXH B PG 53

EXHIBIT C

Europäisches Patentamt
European Patent Office
Office européen des brevets

Search results

2 items found, displaying all
Search term(s): txt = salubrious and txt = pharmaceutical

PROCESS FOR TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS, RHEUMATOID ARTHRITIS, TREMORS/PARKINSON'S DISEASE, MULTIPLE SCLEROSIS, NON-VIRAL BASED CANCERS, ALZHEIMER'S DISEASE, MUSCULAR DYSTROPHY, ATTENTION DEFICIT DISORDER, ATTENTION DEFICIT HYPERACTIVITY DISORDER, COMPLEX REGIONAL PAIN SYNDROME, DIABETES, NEUROPATHIC PAIN, SPIDER ARTHRITIS, WEST NILE VIRUS, FIBROMYALGIA, SHINGLES, GOUT, MIGRAINE HEADACHES, SENILE DEMENTIA, POST POLIO SYNDROME, CENTRAL VIRUS DEAFNESS, ASTHMA, CHRONIC PAIN OF UNKNOWN ORIGIN AND HEPATITIS C				
Application No. EP11769524	**Publication No.** EP2558119	**Applicant** Salubrious Pharmaceutical LLC	**Representative** Daniels, Jeffrey Nicholas, et al	**IPC** A61K39/13
PROCESS FOR TREATMENT OF RHEUMATOID ARTHRITIS, TREMORS/PARKINSON'S DISEASE, MULTIPLE SCLEROSIS AND NON-VIRAL BASED CANCERS				
Application No. EP08816736	**Publication No.** EP2334325	**Applicant** Salubrious Pharmaceutical LLC Salubrious Pharmaceutical LLC	**Representative** Daniels, Jeffrey Nicholas	**IPC** A61K39/00 A61K39/38 A61K39/12 (+1)

2 items found, displaying all
Search term(s): txt = salubrious and txt = pharmaceutical

EXH C PG 54

EXHIBIT D

Verdries, Annie

From: Verdries, Annie
Sent: Friday, October 09, 2015 1:54 PM
To: tkquick@gmail.com
Subject: Salubrious

Mr. Quick
We are proposed counsel for the trustee.
Is Mr. Nelson interested in purchasing the intellectual property from the bankruptcy estate?
If so, please make us an offer.
Thanks.

Sent from my iPhone
Annie Verdries
Partner
Annie.Verdries@lewisbrisbois.com
Lewis Brisbois Bisgaard & Smith LLP
650 Town Center Drive, Suite 1400
Costa Mesa, CA 92626
T: 714.668.5552 F: 714.850.1030

www.LewisBrisbois.com

EXH D PG 55

Verdries, Annie

From: Tim Quick <tkquick@gmail.com>
Sent: Tuesday, February 02, 2016 4:07 PM
To: Verdries, Annie
Subject: 2:15-11118 Salubrious Pharmaceutical
Attachments: Salubrious LLC docs.pdf

Ms. Verdies,

Attached please find the State of Delaware LLC certificate of formation for the Debtor and the documents initiating the only bank account that I am aware of for the Debtor. The bank account was opened only for the purpose of the Debtors Chapter 11. There are no checks over $5,000.00 drawn on the account. I don't believe there has ever been more than $100.00 in the account.

There are no minute books for Debtor, no contracts re IP, no membership subscription agreements or copies of checks for payment per the Debtor. There are also no agreements for funding of the development of IP.

I have asked the Debtor to provide further documents,as requested by your office.

--
Timothy K. Quick
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3502 Katella Avenue, Suite 207
Los Alamitos, California 90720
Tel (562) 799-6020
Fax (877) 803-7252

EXH D PG 56